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RESEARCH ARTICLE

Poland - National regulation on processing data for scientific research purposes and biobanking activities

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Abstract
Biobanks raise great hopes for future research that can help understand many diseases and find ways to treat them. The article aims to study the legislative acts regulating the activities of biobanks in Poland and formulate recommendations for improving the legal regulation of biobanking. This article proposes several key recommendations which include the development of a legal framework to regulate the collection of human biological materials for their submission to biobanks, regulation of the organizational and legal structure of biobanks, and the establishment of a system of standards and rules for the functioning of biobanks. These recommendations can help establish an effective system of biobanks in Poland that provides for the systematic collection and storage of biological samples and promoted medical research for innovative treatments, diagnostic methods, and disease monitoring.

Keywords: biobank; public health system; biorepository; protection of donor information; biological samples.

Introduction

Since the comprehension of the value of each person is constantly changing and improving, a quality healthcare system plays a crucial role in ensuring human rights to life and medical care within a single state or region and throughout the planet. In many countries, national healthcare systems are being reformed to ensure access to effective medicines for everyone and to improve quality and prolong people's lives. Law represents a regulator of social relations that helps to expand and simplify people's access to quality healthcare services and medicines.

A component of the infrastructure of the health care system is a biobank - a storage facility intended for the storage of human biological material. The imperfection of the legislation leads to the problem of legal regulation of biobank activities at the international and national levels. Furthermore, the problem is exacerbated by the absence of normative legal acts that would comprehensively regulate such activity and consider its features. The activities of biobanks cause ethical and legal debates and do not lose their relevance for researchers in various fields. In world practice, there are different approaches to the legal regulation and management of biobanks and the funding of their activities.

Biobanks show great promise for future research that can help understand many diseases and find ways to treat them. However, health research requires extensive collections of well-characterized samples from well-defined patients and their storage in conditions that guarantee access to the data and the protection of donor information. The two important notions the authors operate within this article are biorepository and biobank, which differ in the degree of detail according to the accepted recommendations. However, the analysis shows that these two variants are acceptable for domestic legislation.

A biorepository is a place where biological materials are collected, processed, stored, and distributed to support multidisciplinary, multicenter, and other research projects. Animal samples, samples of human biological materials, and other living organisms can be stored in biorepositories. A biobank is a type of biorepository that stores organized collections of human biological samples and related information for research purposes.

It is difficult to realize the value of samples placed in cryo-storage because scientists themselves sometimes do not even suspect what research they will conduct in a few years and what opportunities biobanks will be able to offer their clients. However, the pace of development in this direction and its ambiguity have already caused many concerns among lawyers and experts in biobanking. Along with the notion of biobanking, the authors also dwell on such a phenomenon as genetic testing. Genetic testing is a laboratory analysis conducted to obtain data on one or another aspect of a person's genetic status.

The principles of predictive, preventive, and personalized medicine (PPPM) are fundamental for the development of medical science all over the world since the need to reduce the costs of medical care, the development of resistant forms of diseases, and numerous side effects of pharmaceutical drugs are the main prerequisites for the search for alternative and

effective treatment methods. The rapid technological development of synthetic biology, epigenetics, and pharmacogenetic examination methods makes it possible to develop individual diagnostic and therapeutic systems for each patient. Given the above, biobanks are essential for interdisciplinary and other scientific research, effective interaction, and international cooperation. Furthermore, a single system of operational procedures between biobanks in different countries becomes crucial for stimulating innovation processes and competition and increasing public trust in the public health system.

Biobanking and Biomolecular Resources Research Infrastructure – European Research Infrastructure Consortium (BBMRI - ERIC) was established in the frame of Article 187 of the Treaty on the Functioning of the European Union (Consolidated version, 2012) in 2013. It enables the exchange of biological samples and data related to them for scientific purposes between European countries. Poland became a full member of this European network in 2016 (Witoń et al., 2017).

The Polish network of biobanks has been operating under the auspices of the Ministry of Science since 2017. It has already united 43 biobanks and is constantly looking for new units to connect with. The network should unite Polish scientists who are engaged in obtaining, collecting, and researching biological material. The vast majority of biobanks are created in hospitals and are state institutions. Some of them are specialized, as in the case of the brain cell biobank (located at the Institute of Psychiatry and Neurology in Warsaw). Some biobanks are managed by private organizations, e.g., pharmaceutical and biotech companies (Kozera et al., 2018).

Current legal, ethical, and social aspects of biobanking are comprehensively covered in the works of such foreign researchers as M. A. Bobinski (2018), D. Krekora-Zając (2019), K. Łakomiec (2014), A. Mednis (2018), J. Pawlikowski (2015), and others. D. Krekora-Zajoc studied how representatives of the doctrine of law, experts in bioethics, and sociologists interpreted the principles and standards of biobank functioning in Poland through the prism of fundamental human rights, constitutional provisions, and individual rights. K. Lakomets devoted the research to the analysis of the activity of population biobanks. It is based on the definition of biobanks as long-term programs for collecting and storing genetic material and information obtained from it, which (within the framework of these programs) is associated with various data related to the donor (the state of health, living conditions, demographic information, etc.). The purpose of the article is to study the legislative acts regulating the activities of biobanks in Poland and formulate recommendations for improving the legal regulation of biobanking.

Given the purpose, tasks, object, and subject of this research, the authors used general scientific and special methods of scientific knowledge. General scientific methods, such as dialectical, systematic, and formal-logical analysis, are fundamental legal techniques and means of research. These methods are fully embodied in each research subdivision and act as a worldview and epistemological justification of cognitive activity. In the context of the analyzed problem, comparative legal and dogmatic (formal legal) methods were the most acceptable among the special research methods used in this article.

The comparative legal method made it possible to identify similar and different approaches to similar legal problems, considered in the framework of this study, in Poland and other countries. In turn, it helped to substantiate the expansion of the field of legal relations, the object of which is biobanking. The formal legal (dogmatic) method was applied to analyze and interpret the content of legal provisions in the field of biobanking activity.

The authors of this article resorted to the modeling method to outline the prospects for developing and improving legislation in this area. This methodological approach made it possible to investigate the legal aspect of relations related to the creation and use of biobanks in more detail and systematically. The dialectical method helped clarify the essence, regularities, and trends of legal regulation of data processing for research purposes and the protection of the rights of participants in legal relations arising in this area.

The formal-logical method provided for defining the notion of biobanking and determining its role and significance in the modern world. The system analysis method made it possible to determine the means of state control of data processing for scientific and technical activities and study the rights of researchers, donors, and patients in biobanking. All the applied methods were interdependent and interconnected, which provided for the completeness, comprehensiveness, and objectivity of this study.

Regulation of Biobanking Activities: Comparison of Biobanking Laws in Different Countries

The creation of biological repositories (biobanks) is essential for developing innovative medicines and introducing the principles of personalized medicine into the national healthcare system. Biobanks have appeared in many countries since 2014, which, in turn, led to the emergence of a corresponding legal framework at the international level and the level of

national legislation. However, there is no unified terminological base used in the field of biobanking. The definitions of biorepository and biobank differ in the degree of detail according to the accepted recommendations. However, the analysis shows that these two variants are acceptable for domestic legislation.

A biorepository is a place where biological materials are collected, processed, stored, and distributed to support multidisciplinary, multicenter, and other research projects. Animal samples, samples of human biological materials, and other living organisms can be stored in biorepositories. A biobank is a type of biorepository that stores organized collections of human biological samples and related information for research purposes. The Organization for Economic Co-operation and Development (OECD) defines biobanks as structured resources that can be used for genetic research and include the following: (i) human biological materials and(or) the information obtained as the result of the analysis of human biological materials; (ii) extended information related to the above.

The term "biobank" often refers to a biorepository designed for participation in research rather than in diagnostic programs. The non-unified terminology for different types of repositories leads to different regulatory regimes and procedures for obtaining permissions. The collection and storage of organs, tissues, cells, and biological products (DNA, proteins, hormones) for therapy, diagnosis, and treatment have long been the competence of laboratories and healthcare institutions. Human biological samples needed for research are obtained from various resources. However, the majority come from the following manipulations during the provision of medical care: surgical materials, medical waste generated during diagnostic tests (blood, other fluids, cytological samples, biopsy samples), remnants of phytoplacenta materials (placenta and cord blood), abortive materials, material obtained during procedures using assisted reproductive technologies, etc. In addition, some countries, such as Estonia, have established many population biobanks. All of the above materials can be provided for biological research directly during the procedure or obtained based on prior informed consent for use in specific biological research (Bobinski, 2018; Tavolzhanska et al, 2020).

Existing biobanks in the world can be classified according to the following criteria:

1) by purpose (archival, museum, clinical, forensic, research, transplantation);
2) according to the selection criteria of biological material (biobank of cardiological, endocrinological, or oncological diseases, population biobank, stem cell biobank, umbilical cord blood biobank, genetic information biobank);
3) by a form of ownership (private or public);
4) according to the criterion of the purpose of economic activity (commercial and non-commercial);
5) by a form of existence (virtual and real).

Biobanks act as intermediaries between donors of biological material and pharmaceutical, diagnostic, or biotechnology companies, contract research organizations, scientific institutions, educational institutions, researchers, and scientists. The International Society for Biological and Environmental Repositories (ISBER) coordinates the activity of biobanks and biorepositories at the international level.

Legal regulation of biobanking, when compared to classical institutions, is a relatively new area. However, its history dates back more than a decade and a half. Particular approaches to the regulation of biobanking have already been formed in Europe, Asia, and the USA. For example, Belgium, Hungary, Israel, Iceland, Spain, Finland, Sweden, and Estonia have adopted special laws to regulate biobanking issues.

This group, in turn, can be divided into two subgroups. The Nordic countries of Finland, Sweden, Estonia, and Iceland belong to the first subgroup that has adopted laws highly specialized on biobanking issues. The second subgroup involves countries whose laws regulate the issues of biobanking and closely related issues, such as the regulation of genetic research. These may include Israel, Spain, and Hungary (Chen et al., 2015).

In the UK, USA, France, and China, there are no special laws on biobanking but separate legal norms related to biobanking issues, incorporated into broader regulations on public health, information protection, non-discrimination, etc. Here, one can see a fairly wide range of approaches in terms of the level of regulation. Thus, some countries (for example, France) regulate the issue under the study at the legislative level, albeit fragmentarily. Other countries, such as China, control the issues related to biobanking exclusively at the sub-legislative level, even though projects of legislative regulation are being discussed. In many countries, there is a combination of approaches, which means that particular norms are adopted at the legislative level, and some regulation is carried out at the sub-legislative level.

The laws on biobanks adopted in Nordic countries are largely unified. It is important to pay attention to the following generalized characteristics. The norms of these laws adopted the legal approaches laid down in international acts in the field of regulation of genetic research and human rights, primarily in the

Convention for the Protection of Human Rights and Human Dignity in Connection with the Application of Achievements of Biology and Medicine of 1997.

Biobanks are obliged to ensure compliance with the following mandatory requirements:

- voluntary informed consent of donors, which can be withdrawn;
- confidentiality of materials;
- ethical review of the research program;
- appropriate conditions for the storage of collected biological materials and their confidentiality and physical safety;
- regular publication of reports.

All laws ensure national control and national jurisdiction of biobanks. Thus, Article 5 of the Law of Iceland explicitly states that only a national organization can be a biobank. According to Estonian Law, the primary operator of the Gene Bank is the University of Tartu (para. 3), which can delegate its rights to national organizations that have received the appropriate permission (para. 4). All laws emphasize the need to obtain a national license or another permit.

In some cases (for example, in Article 10 of the Law of Iceland), it is indicated that a biobank is not the owner of biological materials and can dispose of them only within the limits specified in the license. Laws adopted in the early 2000s contain fairly general requirements for the establishment and operation of biobanks (for example, the Swedish Law of 2002). Since there was a need to specify the issues of biobank management or conditions for the transfer of information, the Law of Iceland was amended repeatedly, and the most significant amendments were noticed in 2014. At the same time, the Council of Europe's Recommendation on research on biological materials of human origin as of 2016 set more detailed regulatory standards than those that could be traced in the national laws of the Nordic countries (Rial-Sebbag & Pigeon, 2015).

Current Regulation of Genetic Testing and Biobanking in Poland

Regulation of the issue of genetic testing and biobanking has been announced in Poland for the last few years. Currently, this area is partially regulated by the following legal acts (Uchańska 2018): the Act on Laboratory Diagnostics (Ustawa z dnia 27 lipca 2001 r.); the Act on Patient's Rights and the Patient"s Rights Ombudsman (Ustawa z dnia 6 listopada 2008 r. o prawach pacjenta); the Act on Accreditation in Health Care (Ustawa z dnia 6 listopada 2008 r. o akredytacji w ochronie zdrowia); the Act on the Protection of Personal Data (Ustawa z dnia 10 maja 2018 r.); the Act on the Collection, Storage, and Transplantation of Cells, Tissues, and Organs (Ustawa z dnia 1 lipca 2005 r.); the Act on the Information System in Health Care (Ustawa z dnia 28 kwietnia 2011 r.); the Act on Medical Activity (Ustawa z dnia 15 kwietnia 2011 r.); the Act on the Professions of Physician and Dentist (Ustawa z dnia 5 grudnia 1996 r.); the Regulation on the Requirements to be Met by a Medical Diagnostic Laboratory (Rozporządzenie Ministra Zdrowia z dnia 3 marca 2004 r.); Regulation on Medical Records (Rozporządzenie Ministra Zdrowia z dnia 6 kwietnia 2020 r.); the Regulation on Quality Standards for Medical Diagnostic and Microbiological Laboratories (Rozporządzenie Ministra Zdrowia z dnia 23 marca 2006 r.); the Regulation on the Model Document "The right to practice the profession of laboratory diagnostician" (Rozporządzenie Ministra Zdrowia z dnia 16 lipca 2004 r.).

The activity of biobank institutions and their possibility of obtaining a license is precisely regulated in Poland. However, the requirements for the protection of the right to privacy and intimacy or the right to secrecy in the context of genetic research are insufficiently regulated. Even though the General Data Protection Regulation has been implemented in Poland, the problem of regulation of special data protection is still acute (Judgment of the Constitutional Tribunal of 11 October 2016). A group of significant legal problems related to the collection of remuneration for research using human biological material, including genetic research, is still unresolved. The legislation of Poland has not yet regulated issues related to entities authorized to perform such activities, the procedures applied, and the rights of a donor or the rights of people related to a donor. Numerous issues listed above clearly demonstrate the need for urgent, detailed, and prudent regulation of the matter in question.

There is currently no legal definition of biobanks for scientific purposes in Polish law. The definition of a biobank was developed as part of expert work carried out by the Team for Principles of Scientific Research in Biomedicine at the Ministry of Science and Higher Education in 2013–2014 (Łakomiec, 2018). In this sense, a biobank means an organizational unit that collects (collects, processes, stores), distributes, and shares biological material and related data for scientific research; it uses the collected resources in a repeated and long-term manner and applies specific procedures to preserve the high quality of accumulated resources and to protect the rights of donors under the appropriate supervisory body in the form of a scientific and ethical committee.

Legal Protection of Freedom of Scientific Research and Donor Rights in Poland: Constitutional and Private Law Guarantees

The Polish law lacks not only specific legal regulations for biobanking but also for conducting biomedical research. The Act on the Professions of Physicians and Dentists is the only legal regulation that determines the conduct of scientific research involving human participants (Ustawa z dnia 5 grudnia 1996 r.). It permits to conduct scientific research on a human being as a medical experiment. However, it does not apply to biobanking and scientific research based on a human biological sample. The reasons behind the above are some historical aspects and the definition of a medical experiment in Polish law (Krekora-Zając, 2019a). Thus, currently, biobank regulation remains based on fundamental constitutional freedoms.

The lack of a specific legal regulation of scientific biobanks leads to the need to interpret the rules regarding the admissibility of their operation by the entire legal system, defining the limits of freedom to study human biological samples (Łakomiec, 2014). Freedom of scientific research is one of the fundamental human and civil rights that are directly protected in the Constitution of the Republic of Poland (Konstytucja Rzeczypospolitej Polskiej z dnia 2 kwietnia 1997 r.). According to Art. 73 of the Constitution, every person has the right to freedom of artistic creation, scientific research, publication of their results, and teaching and using cultural goods. This freedom is associated with information acquisition and dissemination, including in the public interest (Królikowski & Szczucki, 2016).

The Constitution provides broad protection to entities exercising the freedom of research. Freedom of research covers not only the scientific activities of scientists whose duties include conducting scientific research but also the activities of other people who, without formal links with the scientific sector, conduct activities consisting in conducting scientific research. The guarantees enshrined in Article 73 of the Constitution protect natural persons and other legal persons against unjustified state interference in the subject and methods of scientific research, as well as the content and techniques of teaching. Such broad protection indicates that scientific freedom is a universal value, and its limitation is possible only when it is necessary to protect other constitutional values (Krekora-Zając, 2019a).

The freedom of scientific research may only be limited based on Article 31 (3) of the Constitution. It is subject to the principle of proportionality. Restrictions may be established in law and only when necessary in a democratic state for its security and public order or the protection of the environment, health, morals, or the freedoms and rights of other people. Furthermore, restrictions should not violate the essence of freedoms and rights (Królikowski & Szczucki, 2016). It is permissible to conduct scientific research where the legal order does not provide clear boundaries and the consequences of breaching them, and the legislator, public administration, and all other entities are obliged to refrain from interfering in this freedom (Krekora-Zając, 2019a).

The concept of scientific research is not defined in the Constitution. Therefore, each entity implementing scientific research in biobanking enjoys constitutional protection. According to the Constitution, the freedom of scientific research is protected as human freedom and does have subjective limitations. The researcher is obliged to adhere to ethical principles resulting from codes of good practices and soft law. The interests of society or scientific objectives should not prevail over the good of the individual. It is necessary to pay respect for the dignity of every human being (Królikowski & Szczucki, 2016). This extends to respect for human bodies and their parts, even after death. The researcher should take care to preserve the confidentiality of all information that could pose a direct or indirect risk to the deceased or their relatives.

Human bodies or their parts do not constitute a source of financial benefits. Researchers and people in charge of collecting human biological material should not stigmatize and discriminate against the donors of material, their families, and people belonging to a specific ethnic group. The activities of collecting, processing, and storing biological material should be undertaken by experts who are experienced in this area and are familiar with legal and ethical aspects related to the collection and long-term storage of human biological material and data (Krekora-Zając, 2019a; Vapniarchuk et al, 2019).

Scientific freedom is also protected under Polish private law. Article 23 of the Civil Code of the Republic of Poland (Ustawa z dnia 23 kwietnia 1964 r.) also encompasses non-pecuniary values accompanying scientific, artistic, inventive, and rationalizing creative activity. The outcomes of scientific research are protected directly by the provisions of Articles 23 and 24 of the Civil Code (Pazdan, 2012).

Since there is no specific act on biobanking and research of human biological samples, donor rights are the subject of the main legal publications on biobanking in Poland. They are derived from fundamental human and personal rights (Krekora-Zając, 2019a). These are the right to privacy guaranteed in Article 47 of the Constitution and the informational autonomy of the individual, which is an element of the right to privacy provided for in Article 51 of the Constitution.

In the context of biobanking, the right to privacy entails the protection of donor privacy, i.e., donor-related information (Pawlikowski, 2015). It covers the protection of personal data processing, the protection against discrimination, and the right to be informed and not to be informed. Since these rights have been substantially amended by the GDPR, the GDPR allows restrictions on the rights of the persons from whom the data originates (Krekora-Zając, 2019a; Krekora-Zając, 2019b; Marciniak et al., 2018; Mednis 2018). This refers, for instance, to the secondary use of personal data for scientific purposes (without obtaining new consent) and the limitation of the right to be forgotten or information obligations of the data controller.

Legal and Practical Challenges in Biobanking: Considerations of Information Autonomy, Incidental Findings, and Ownership of Biological Samples

The Constitutional Tribunal points out that the right to privacy consists of principles and rules relating to various spheres of an individual's life; their common denominator is a guarantee of the individual's right to make autonomous choices while limiting external interference in these choices (Judgment of the Constitutional Tribunal of 24 April 1997). The Constitutional Tribunal also states (Judgment of the Constitutional Tribunal of 25 July 2013) that Article 47 of the Constitution attributes the right to privacy to many different spheres of individual activity. It protects a multi-level network of personal rights and is closely related to the detailed regulation set forth in Articles 30, 48, 49, 50, 51, 53 (1), 53 (7), and 76 of the Constitution. Thus, the subjective constitutional right to privacy, which represents one of the fundamental elements of the axiology of a democratic state ruled by law, has two aspects. The first is the decision-making autonomy of an individual, understood as the possibility of self-determination about one's personal life in the objective, subjective, and temporal aspects. The second is the informational autonomy of an individual, which guarantees, in particular, the individual's ability to independently determine the spheres of accessibility to other subjects of information about themselves.

The conditions for processing information about an individual have been of interest to the Constitutional Tribunal for a long time. The Tribunal expressed its views on the provisions set forth in Articles 47 and 51 of the Constitution and considered their interconnection (Judgment of the Constitutional Tribunal of February 19, 2002; Judgment of the Constitutional Tribunal of November 20, 2002; Judgment of the Constitutional Tribunal of June 20, 2005). In the opinion of the Constitutional Tribunal, Article 47 of the Constitution guarantees the protection of private life. Article 51 of the Constitution guarantees information autonomy, which means the right to decide on the disclosure of information about themselves to others and the right to exercise control over such information if it is in the possession of other entities. The Tribunal also believes that the provisions of Articles 47 and 51 are designed to protect the same value - the sphere of privacy (Judgment of the Constitutional Tribunal of 13 December 2011).

The right to privacy under the Constitution should be considered a body of rules (an institution) which, due to the functional bond, consists of rules that shape an individual's subjective rights and impose certain obligations on the state correlated with these rights (Łakomiec, 2014; Łakomiec, 2018). As noted by the Constitutional Tribunal, the obligation of public authorities to guarantee freedoms and rights has a broader dimension than the prohibition of excessive interference, including the surreptitious obtaining of information about persons by public authorities. In the opinion of the Tribunal, it implies the obligation of the state to create conditions in which citizens can freely exercise their rights and freedoms. The conditions for ensuring freedom and rights are a sense of security in the state and the absence of threats to citizens (Judgment of the Constitutional Tribunal of 30 July 2014). The judgment of the Constitutional Tribunal on genetic information (2016) is of high importance as it describes the principles of collecting biological material for genetic testing.

Although it concerns criminal proceedings, the remarks on the constitutional rules relating to the processing of genetic information are universal (Łakomiec, 2018). The Constitutional Tribunal states that when biological material is taken from a human body, it interferes with its inviolability, the essence of which is related to the inviolability of bodily integrity. It is worth noting that such an intervention was considered a non-invasive method of obtaining tissue, i.e., sampling a smear from the cheek mucosa. The Tribunal emphasized that this act was an interference with personal inviolability (Art. 41 (1) of the Constitution). Further, the Constitutional Tribunal found that the collection of biological material could be considered a restriction of the right to protection of private life. The Tribunal holds, “Due to the amount and nature of the information contained in a sample of human material in the form of the genetic code, the collection of biological materials that are sources for DNA analysis interferes with the sphere of human privacy. Even the mere awareness of the use of this genetic information in the future may cause stress, anxiety, or other adverse effect on the mental integrity of a person. Therefore, the very act of sampling a smear from the cheek mucosa constitutes an

interference with the private sphere of an individual, protected under Article 47 of the Constitution, primarily in the aspect of mental integrity and informational autonomy."

The Constitutional Tribunal also determined whether the collection of a biological sample represented an interference with the information autonomy of an individual. The Tribunal believes that information autonomy involves the right to decide on disclosing information about oneself and the freedom to define the sphere of accessibility to others of their knowledge. Given the above, the obligation to provide samples of biological material, which is very personal information, including the genetic code, constitutes entering the sphere of autonomy information. Article 51 (2) of the Constitution implies the protection of any information about an individual, regardless of the method of its consolidation. In other words, it also protects the genetic information, carried by an isolated DNA sample. This is in line with the views of the Supreme Court, which defines that prepared fragments of tissues and organs may constitute medical documentation (Judgment of the Supreme Court of 9 February 2011; Łakomiec, 2018).

The analysis of the case law and regulations of Poland allowed the authors to highlight two significant problems in the field of biobanking for scientific purposes. One of them is the obligation to provide donors with information relevant to their health discovered somewhat accidentally as part of conducted research (so-called incidental findings). Article 9 of the Act on Patient's Rights and the Patient's Rights Ombudsman determines that the patient has the right to obtain all information about their health. Such information is needed for making an independent and informed decision about the choice of therapy. Therefore, when physicians receive any information, including research relevant to the patient's health, they must disclose it to the patient. However, biobanks are not always informed about the discoveries of the scientists to whom they donate samples; biobanks receive pseudo-anonymous or even non-identifiable data. Thus, this legal obligation can hardly be fulfilled.

Another problem is the identification of the rights to a human biological sample and the rules for transferring it to other research units or researchers. The transfer of samples and data is undertaken based on the Material Transfer Agreement and the Data Transfer Agreement. These contracts are of a model nature. They are prepared by individual biobanks or scientific and medical organizations. They define the rules for submitting a sample or data, set fees, and determine intellectual property rights to the results of tests based on these samples, copyrights to the publication of the results, and the possibility for the recipient to use the samples or data. Patient rights do not involve the protection of samples that are no longer needed for diagnostic or therapeutic processes; they will only be classified as medical waste.

In order to improve the current legislation of Poland, the authors of this article suggest doing the following:

- to follow the standard operating procedures of EU biobanks and provide coding of used material (human biological waste) after mandatory sampling;
- to regulate the requirements regarding the organizational and legal form of the creation of a biobank, the legal basis of its functioning, the form of ownership, and financing at the legislative level;
- to elaborate on the legal mechanism for filling and supplying the biobank with new biological samples (production by pathology departments or health care institutions, exchange with foreign biobanks, temporary use);
- to normatively regulate the issue of ownership of biological samples in the biobank (consolidation of donor rights);
- to develop a system of standards and rules for the functioning of biobanks.

Thus, the creation of an effective system of biobanks in Poland, which considers the ethical and legal components and involves a systematic collection of biological samples obtained from people with various diseases, their storage in appropriate conditions, the development of internal documentation and standard operating procedures, is crucial for the formation and development of domestic science, innovative medicines, and methods of diagnosis and monitoring of diseases.

Conclusion

The rapid technological development of synthetic biology, epigenetics, and pharmacogenetic examination methods makes it possible to develop individual diagnostic and therapeutic systems for each patient. Given the above, biobanks are essential for interdisciplinary and other scientific research, effective interaction, and international cooperation. Furthermore, a single system of operational procedures between biobanks in different countries becomes crucial for stimulating innovation processes and competition and increasing public trust in the public health system.

The imperfection of the legislation leads to the problem of legal regulation of biobank activities at the international and national levels. Furthermore, the problem is exacerbated by the absence of normative legal acts that would comprehensively regulate such activity and consider its features. The activities of

biobanks cause ethical and legal debates and do not lose their relevance for researchers in various fields.

The creation of biological repositories (biobanks) is essential for developing innovative medicines and introducing the principles of personalized medicine into the national healthcare system. Biobanks have appeared in many countries since 2014, which, in turn, led to the emergence of a corresponding legal framework at the international level and the level of national legislation of Poland. However, the legislation of Poland has some imperfections in the field of biobanking, so there is a need to overcome them.

In order to improve the current legislation of Poland, the authors of this article suggest to do the following: develop a legal framework that regulates the legality of sampling human biological materials (both normal and pathologically altered) for submission to the biobank in Poland; to determine the procedure for collecting human biological materials that considers the international experience and the basic principles of biomedical ethics; to elaborate on the legal mechanism for filling and supplying the biobank with new biological samples. Furthermore, there is a need to regulate the requirements regarding the organizational and legal form of creating a biobank, the legal basis of its functioning, and the form of ownership and financing at the legislative level. It is also necessary to normatively regulate the rights of donors and develop a system of standards and rules for the functioning of biobanks.

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