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Legal aspects of biobanking HBS for scientific purposes in Poland

Abstract
Legal issues related to the biobanking of human biological samples are one of the extremely important areas of European law. Biobanks created in Poland as well as the Polish Biobank Network created under the auspices of the Ministry of Science and Higher Education have become a catalyst for the search for solutions and the basis of rights for the functioning of biobanks in Poland as well as the protection of donor rights. Undoubtedly, the lack of legal regulation of biobanks and biomedical research on human biological samples could become a significant problem limiting the development of biobanking and conducting scientific research in Poland. The research attempts to show how representatives of the doctrine of law, bioethics and sociologists have interpreted the principles and standards of biobank operation in Poland from basic human rights, constitutional norms and personal rights.

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1. Introduction

Conducting scientific research on human biological samples has become one of the most important elements of acquiring knowledge about humans and on the etiology of many diseases, both population and rare. For years, such research has been conducted around the world, but it seems that only in the last ten years the idea of conducting large research on human biological samples from large biorepositories, such as biobanks, has flourished.

The development of such research poses new challenges not only to geneticists and biologists, but also to lawyers. The result is that new legal issues are arising of a character distinct both from medical law and traditionally understood private law. M. Grzymkowska wrote that "the development of biomedicine touches on one of the basic paradigms of law, which is the concept of a person"[2]. Considering the values it is supposed to protect (social solidarity, public interest, the interest of future generations) the law regulating the activities of biobanks departs to a large extent from its particularity as related to national legal systems; this, in turn, implies that the considerations of representatives of foreign and national doctrine depart from universal meanings and the possibility of referring to different legal orders.

In Poland, the need for legal regulation of biobanking has been postulated for years[3]. However, despite the lack of specific legislation, biobanks regulation remains based on fundamental constitutional freedoms. The subject matter of the considerations in this study will be a presentation of the specificity of legal aspects of biobanks in Poland and the decoding of relevant standards from the Polish legal system[4].

2. The idea of biobanking and biobanks in Poland

"Biobank" is a term for various types of biological sample collections with related databases, which have a certain level of accessibility, availability and exchange for scientific purposes. Thus, a biobank is an institution whose main purpose is to store tissues, cells and human organs[5].

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2 M. Grzymkowska, *Standardy bioetyczne w prawie europejskiej*, Warszawa 2009, p. 28.

3 D. Krekora-Zając, *O konieczności regulacji prawnej biobanków*, "Państwo i Prawo" 2012, no. 7, pp. 64–77.

4 The work was supported by the National Science Center, Poland Grant Number 2016/23/D/HS5/0041.

5 J. Pawlikowski, *Biobankowanie ludzkiego materiału biologicznego dla celów badań naukowych – aspekty organizacyjne, etyczne, prawne i społeczne*, Lublin 2013, p. 12.

Undoubtedly, biobanks all over the world, including Europe, are now experiencing a "boom". They are both private and public institutions that collect samples of genetic material for scientific, clinical or policing purposes[6].

Biobanks are created encompassing only the collection of samples from people with a specific mutation, e.g. a specific genetic mutation, as well as population biobanks that store and use genetic material collected from different people regardless of their specific mutations belonging to a specific population[7]. The former make it possible for researchers to work on the etiology and methods of treatment of specific diseases, while the latter make it possible to learn about so-called population diseases occurring with high frequency in humans[8].

Thanks to biobanks, scientists can use samples not only taken from their patients/donors, but can conduct research on a large amount of biological material from different donors[9]. Therefore, it is impossible not to appreciate the great importance of biobanks for the possibility of researching many diseases and for finding medicines for some of them. Thanks to the existence of biobanks of human tissues, it is possible to perform scientific research on a very large number of samples that are not otherwise available to scientists. Without biobanks, it would not be possible to develop medicine, pharmacy or genetics[10].

Nine years ago the idea of biobanking was recognized by *Time* magazine as one of the leading ideas that can change the world[11], and in 2013, on the basis of Art. 187 TFEU[12], the Biobanking and Biomolecular Resources Research Infrastructure ERIC was established, which became a network enabling the exchange of biological samples and data related to them for scientific purposes between European countries. Poland initially participated in the work of BBMRI. The status of ERIC as an observer evolved to that of a full member of this European network in 2016[13].

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6 D. Krekora-Zając, *Zgoda na przetwarzanie danych przez biobanki dla celów naukowych* [in:] A. Białek, M. Wróblewski (ed.), *Wybrane aspekty praw człowieka a bioetyka,* Warszawa 2016, p. 52.

7 E. Bartnik, *Biobanki jaki przyszłość nauki*, "Studia Iuridica" 2018, no. 73, pp. 9–13.

8 J. Pawlikowski, *Ochrona praw dawców w wybranych europejskich biobankach populacyjnych*, "Diametros" 2012, no. 32, pp. 91–92.

9 C. C. George, *The European Bank for Induces Pluripotent Stem Cells (EBiSC): Opportunities & Challenges Through Public–Private Collaboration*, "Stidia Iuridica" 2016, no. 73, p. 29.

10 Ibid.

11 A. Park, *10 Ideas Changing the World Right Now. Biobanks,* Time, 12.03.2009, http://content.time.com/time/specials/packages/article/0,28804,1884779_1884782_1884766,00.html [access: 22.07.2019].

12 J. Reichel, *EU Governance for Research and Ethics in Biobank* [in:] D. Mascalzoni (ed.), *Ethics, Law and Governance of Biobanking. National, European and International Approaches*, Spiringer 2015, p. 175.

13 M. Witoń, D. Strapagiel, J. Gleńska-Olender, A. Chróścicka, K. Ferdyn, J. Skokowski, L. Kalinowski, J. Pawlikowski, B. Marciniak, M. Pasterk, A. Matera-Witkiewicz, Ł. Kozera,

Currently, the activity of biobanks in Poland is not licensed or registered by the state, therefore it is not possible to precisely determine the number of biobanks and their organizational rules. As part of a project carried out by a consortium of Polish biobanks, BBMRI.pl, and funded by the Ministry of Science and Higher Education, work on the organization of a biobank network has been underway since 2017. At the moment, the Polish Network of Biobanks has over 42 members and observers[14]. The vast majority of biobanks are created in hospitals and are public entities. Some of them are completely unique, as in the case of brain cell biobanks (located at the Institute of Psychiatry and Neurology in Warsaw), which constitute one of the largest collections of such cells in Europe. There are also biobanks / biorepositories run by private entities, e.g. pharmaceutical companies and biotechnology companies. In addition, it should be emphasized that the first three biobanks of the general population have been founded in Wrocław, Gdańsk and Łódź[15].

3. Conducting biomedical research on human biological samples under the Act on the Professions of Physician and Dentist and The Code of Medical Ethics

The Polish law lacks not only specific legal regulations for biobanking, but also for conducting biomedical research. In practice, this means that the only special legal regulation relating to the conduct of scientific research involving humans is the Act on the Professions of Physician and Dentist[16]. On the basis of this Act, it is permissible to conduct scientific research on a human being as a medical experiment. These regulations, however, do not apply to biobanking and conducting scientific research on a human biological sample, both due to the construction of the notion of a medical experiment in Polish law and to historical reasons.

The necessity to create legal norms with regard to human experiments throughout Europe arose from the result of the Nuremberg trials, in which the

Organization of BBMRI. Pl: The Polish Biobanking Network, "Biopreservation and Biobanking" 2017, no. 3, pp. 264–269.

14 A. Chruścicka, A. Paluch, A. Matera-Witkiewicz, *Polska Sieć Biobanków rozwija się i zaprasza do współpracy*, Biotechnologia.pl, 30.07.3019, https://biotechnologia.pl/biotechnologia/polska-siec-biobankow-rozwija-sie-i-zaprasza-do-wspolpracy,18949 [access: 30.07.2019].

15 Ł. Kozera, D. Stapagiel, J. Gleńska-Olender, A. Chróścicka, K. Ferdyn, J. Skokowski, L. Kalinowski, J. Pawlikowski, B. Marciniak, M. Pasterk, A. Matera-Witkiewicz, M. Lewandowska-Szumieł, M. Piast, M. Witoń, *Biobankowanie ludzkiego materiału biologicznego dla celów naukowych w Polsce i Europie,* "Studia Iuridica" 2018, no. 73, pp. 13–29.

16 Ustawa o zawodach lekarza i lekarza dentysty z 5 grudnia 1996 r., Dz.U. 2019, item 537.

cruelty of human experience was demonstrated[17]. Legal norms have been created in both international law and in national legal regimes, stating fairly restrictive rules for conducting experiments on people so that such cruel practices will never happen again. The aforementioned Nuremberg Code set out ten basic principles for conducting experiments on people[18].

In Polish national law, conducting an experiment is only allowed on the basis of Art. 39 of the Constitution[19] and Art. 21–29 of the Act on the Professions of Physician and Dentist. According to Art. 39 of the Constitution, "No one can be subjected to scientific experiments, including medical, without voluntary consent." The constitutional regulation therefore only refers to experiments conducted on humans, but not on human biological samples[20]. L. Kubicki[21] pointed out in an article that a study that is not carried out directly on a human being, but would involve manipulation of environmental factors that could pose a threat to humans, can also be considered a medical experiment performed on a human. Similarly, Art. 21 of the Act on the Professions of Physician and Dentist indicates that a medical experiment can be carried out only on humans, not on human biological samples[22].

The rules of medical experiments have been regulated in Polish law for years and elaborated by prominent representatives of the legal doctrine[23].

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17 https://avalon.law.yale.edu/imt/judgen.asp [access: 30.07.2019].

18 A. Wnukiewicz-Kozłowska, Eksperyment Medyczny na organizmie ludzkim w prawie międzynarodowym i europejskim, Wrocław 2004, pp. 39–46.

19 Constitution of the Republic of Poland of 2 April 1997, (OJ L No. 78., item 483).

20 M. Królikowski, K. Szczucki [in:] M. Safjan, L. Bosek (ed.), *Konstytucja RP*, vol. 1, *Komentarz art. 1–86*, Warszawa 2016, p. 957.

21 L. Kubicki, *Medyczny eksperyment badawczy (warunki dopuszczalności w prawie polskim)*, "Państwo i Prawo" 1988, no. 7, p. 54.

22 M. Gałązka, L. Bosek, Eksperyment medyczny [in:] L. Bosek, A. Wnukiewicz-Kozłowska (ed.), *Szczegółowe świadczenia zdrowotne*, Warszawa 2018, p. 54.

23 A. Wnukiewicz-Kozłowska, *Eksperyment Medyczny na organizmie ludzkim w prawie międzynarodowym i europejskim*, Wrocław 2004; L. Bosek, *Podstawy i zasady odpowiedzialności cywilnej za szkodę wyrządzona uczestnikowi eksperymentu medycznego – de lege ferenda i de lege lata* [in:] M. Boratyńska (ed.), *Ochrona strony słabszej stosunku prawnego. Księga jubileuszowa ofiarowana Profesorowi Adamowi Zielińskiemu*, Warszawa 2016, pp. 495–523; P. Konieczniak, *Eksperyment medyczny* [in:] E. Zielińska, M. Boratyńska, P. Konieczniak (ed.), *Regulacja Prawna czynności medycznych*, Warszawa 2018, pp. 64–113; M. Gałązka, L. Bosek, *Eksperyment medyczny* [in:] L. Bosek, A. Wnukiewicz-Kozłowska (ed.), *Szczegółowe świadczenia zdrowotne* Warszawa 2018, pp. 45–84; M. Sośniak, *Uwarunkowania prawne dopuszczalności eksperymentów medycznych na ludziach*, "Państwo i Prawo" 1985, no. 5, pp. 31–42; J. Różyńska, *Eksperyment genetyczny dwa w jednym?,* "Prawo i Medycyna" 2016, no. 4, pp. 5–31; R. Kubiak, *Zgoda uczestnika eksperymentu cz I*, "Prawo i Medycyna" 2000, no. 8, pp. 44–59; Id., *Warunki prawne dopuszczalności eksperymentów medycznych – wątpliwości dotyczące regulacji w świetle konwencji bioetycznej* [in:] O. Nawrot, A. Wnukiewicz-Kozłowska (ed.), *Temida w dobie rewolucji biotechnologicznej. Wybrane problemy bioprawa*, Gdańsk 2015, pp. 133–162; L. Kubicki, *Medyczny*

Therefore, in Polish law a medical experiment is always an experiment on a human being[24] – it consists in giving the participant experimental substances, using certain research methods, and thus always an intervention on the human body – violation of integrity. The risks[25] associated with a medical experiment are real threats to the life and health of the participant in such an experiment. For this reason, in Polish law, it was accepted that such an experiment is possible only in exceptional situations, including after obtaining the explicit consent of the participant, but also after the approval of an entity independent from the participant of the intention to carry out the experiment, i.e. the bioethics commission.

In addition, the field of biobanking entails completely different threats to the participants than in the case of a medical experiment. As regards biobanking in law, European[26] and American[27] doctrine, it is indicated that these threats are related to the privacy[28] and autonomy of donors, but never to life and health.

In the doctrine, there are also sometimes references to the notion of a genetic experiment (based on the Code of Medical Ethics). According to A. Wnukiewicz-Kozłowska[29], all forms of application of genetics to the human

eksperyment badawczy (warunki dopuszczalności w prawie polskim), "Państwo i Prawo" 1988, no. 7, pp. 54–64, P. Konieczniak, *Eksperyment naukowy i techniczny a porządek prawny*, Warszawa 2013; U. Olędzka, *Eksperyment medyczny w stanach nagłych i stanach bezpośredniego narażania życia*, "Prawo i Medycyna" 2004, no. 16, pp. 112–115; M. Kopeć, *Ustawa o zawodach lekarza i lekarza dentysty. Komentarz*, Warszawa 2016, pp. 625–656; K. Sakowski, *Eksperyment medyczny* [in:] E. Zielińska (ed.), *Ustawa o zawodach lekarza i lekarza dentysty. Komentarz*, Warszawa 2014, pp. 501–553; J. Brańszyński, *Podstawy badań eksperymentalnych*, Warszawa 1992; M. Czarkowski, J. Różyńska, *Świadoma zgoda na udział w eksperymencie medycznym*, Warszawa 2008; M. Nestorowicz, *Eksperyment medyczny w świetle prawa (podstawy prawne, odpowiedzialność ubezpieczenia)* "Prawo i Medycyna" 2004 special issue, pp. 27–38; M. Nowak, *Prawne formy zgody pacjenta na eksperyment medyczny (zagadnienia cywilnoprawne)*. "Prawo i Medycyna" 2005, no. 3, pp. 45–57; M. Safjan *Wybrane aspekty eksperymentów medycznych na człowieku (problem legalności i odpowiedzialności cywilnej),* "Studia Iuridica" 1994, vol. XXVI, pp. 65–89.

24 P. Konieczniak, *Eksperyment medyczny…* p. 78.

25 L. Bosek, M. Gałązka, *The doctrine indicates the fact that it is controversial to define an acceptable level of such risk* [in:] *Szczegołowe świadczenia zdrowotne…* p. 72.

26 H. Gottwei, *Biobanks for Europe. A challenge for governance. Report of the Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research,* Luxemburg 2012.

27 S. J. Carnahan, *Biobanking newborn bloodspots for genetic research without consent,* "Journal of Health Care and Policy" 2011, no. 14, pp. 299–330.

28 S. Penasa, I. de Mideuel Beriain, C. Basbosa, A. Białek, T. Chortara, A.D. Pereira, P.N. Juménez, T. Sroka, M. Tomasi, *The EU General Data Protection Regulation: How will it impact the regulation of research biobanks? Setting the legal frame in the Mediterranean and Eastern European area*, Medical Law International, 02.04.2018, https://doi.org/10.1177/0968533218765044 [access: 21.08.2019].

29 A. Wnukiewicz-Kozłowska, *Eksperyment medyczny…* p. 145.

body constitute a genetic experiment (research on human embryos in vitro as well as genetic tests, genetic manipulations, gene therapy and scientific explanation of the causes and mechanisms of inheritance are genetic experiments). This position is also shared in publications by M. Świderska[30]. The Code of Medical Ethics also establishes that a physician participating in research aimed at identifying the carrier of a disease gene or genetic susceptibility to illness can only conduct it for health purposes, or as scientific research related to such purposes after obtaining the patient's consent and providing a genetic consultation. Therefore, it should be stressed that Art. 51h of the Code of Medical Ethics does not recognize genetic testing for scientific purposes as a medical experiment.

In summary, six main reasons should be indicated as to why biobanking cannot be considered a medical experiment.

First of all, as demonstrated by the analysis, an experiment consists in affecting the human body; this may be a threat to one's life or health, but biobanking does not refer to human intervention, and the sampling itself is not very invasive (most often it involves collection of saliva, urine, blood or the use of biological samples that remain after medical procedures).

Secondly, at the time of obtaining a sample, it is not possible to inform the donor about any subsequent scope of research on the sample. This sample can be used for several decades after collection in various studies conducted by researchers from multiple scientific centers.

Thirdly, it is not possible to obtain consent *in concreto* for each research project – the idea of biobanking assumes that researchers use ready-made cohorts and do not go through the process of obtaining consents in each case. Obtaining such specific consent in every case would undoubtedly be an excessive burden on the donor, who would have to return in each case to the biobank. In the European discussion on biobanking, different conceptions of consent are adopted, though increasingly the need to obtain broad consent or switch to an opt-out system is indicated.

Fourthly, obtaining separate permission from a bioethical commission for each study would make it essentially pointless to create biobanks, since every researcher would have to go through the procedure for registration of a medical experiment. A good and hitherto commonly used standard is obtaining the consent of a bioethics commission for a research project rather than for a medical experiment.

Fifthly, it should be clearly stressed that research on human biological samples within biobanks is conducted not only by physicians but also by biologists, geneticists, biotechnologists and other researchers.

30 M. Świderska, *Zgoda pacjenta na zabieg medyczny*, Toruń 2007, p. 314.

Sixthly, in Poland there are pediatric biobanks, and conducting an experiment on children which does not provide them with a therapeutic benefit is legally prohibited.

4. Biobanking as an emanation of the constitutional freedom of scientific research

Because there is no specific legal regulation regarding scientific biobanks, the rules regarding the admissibility of their functioning should be interpreted from the legal system as a whole, thus defining the boundaries of research on human biological samples within which they can operate and indicating the boundaries of this freedom[31].

Freedom of scientific research is one of the fundamental human and civil rights protected directly in the Polish Constitution[32]. According to Art. 73 of the Constitution, everyone is guaranteed the freedom of artistic creation, scientific research and the proclamation of their results, freedom of teaching and the freedom to use cultural goods. It is pointed out that this freedom is most widely associated with the acquisition and dissemination of information also in the public interest[33].

The Constitution grants broad protection to entities exercising the freedom of research – it does not limit the scope of freedom of scientific research. The freedom under consideration encompasses the research activities not only of scientific employees whose duties include conducting scientific research, but also the activities of other people who, also without any formal connections with the scientific sector, carry out activities consisting in conducting scientific research. The guarantees contained in Art. 73 of the Constitution protect the individual and other legal entities from unjustified interference by the state in the subject matter and methods of scientific research as well as in the content and methods of teaching. Such a broad protection indicates directly that scientific freedom is a universal value, and its limitation is possible only when necessary for the protection of other constitutional values. Constitutional

31 K. Łakomiec, *Wybrane konstytucyjne aspekty funkcjonowania biobanków populacyjnych,* "Państwo i Prawo" 2014, no. 12, pp. 54–64.

32 W. Brzozowski, *Konstytucyjna wolność badań naukowych i ogłaszania ich wyników* [in:] A. Wiktorowska, A. Jakubowski (ed.), *Prawo nauki. Zagadnienia wybrane*, Warszawa 2014, pp. 25–45; S. Gardocki, *Wolność badań naukowch* [in:] *Uniwersalny i regionalny wymiar ochrony praw człowieka. Nowe wyzwania – nowe rozwiązania. vol. 3*, Warszawa 2014, pp. 301–311.

33 M. Królikowski, K. Szczucki [in:] M. Safjan, L. Bosek (ed.), Konstytucja RP…, pp. 1685–1686.

freedoms, including the freedom of scientific research, may be limited only on the basis of Art. 31 para. 3 of the Constitution and are subject to the principle of proportionality[34].

This principle requires that the measures least burdensome on the individual must be chosen from among effective measures restricting the exercise of freedoms and rights, and the legislator makes it a reimbursement when the illness is no more than is necessary for a constitutionally founded and justified purpose. Restrictions may be established in law and only then as are necessary in a democratic state for its security or public order, or for the protection of the environment, health and or morals, or the freedoms and rights of other people – they may not violate the essence of freedoms and rights[35].

This means that in other situations the Constitution establishes the primacy of freedom of scientific research in such a way that where the legal order does not set clear boundaries and the consequences of breaching them, conducting scientific research is permissible, and the legislator, public administration and all other entities are obliged to refrain from interfering in this freedom. The researcher, however, is always obliged to adhere to ethical principles in his work, resulting from codes of good practices and normative documents of a soft-law nature. Above all, he cannot allow a situation in which the interests of society or scientific objectives prevail over the good of the individual. Scientific progress should be made with respect for the dignity[36] of every human being, which also extends to respect for the body and its 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 his relatives. An accepted ethical norm in scientific research is also the principle that the human body or its parts cannot in themselves constitute a source of financial benefits. Researchers and people accumulating human biological material should be characterized by an attitude free of stigmatization and discrimination of the donors of material, their families, as well as persons belonging to a specific ethnic group. The activities of collecting and storing biological material should be done by people with knowledge and experience in the collection, processing and storage of biological material, as well as awareness of legal and ethical aspects related to the collection and long-term storage of human biological material and data.

34 M. Szydło, [in:] M. Safjan, L. Bosek (ed.), *Konstytucja RP. vol. I. Komentarz art. 1–86*, Warszawa 2016, pp. 799–805.

35 M. Królikowski, K. Szczucki, [in:] M. Safjan, L. Bosek (ed.), *Konstytucja RP…*, p. 1686.

36 Ibid., p. 1685.

The Constitution does not define the concept of scientific research. In the Polish law, therefore, each entity implementing the definition of scientific research given above enjoys constitutional protection. There is no doubt that the constitutional norm in this area is quite general, and therefore the principles of conducting research on human cells and tissues should be regulated by a lower-order act.

Scientific freedom is also protected under Polish private law. The Polish Civil Code in Art. 23 also encompasses non-pecuniary values accompanying scientific, artistic, inventive and rationalizing creative activity. According to P. Pazdan[37], the products of scientific research are protected directly by the provisions of Art. 23 and 24 of the Civil Code. This means that an individual whose scientific activity is threatened by someone else's activity may demand the cessation of such conduct, and if property damage resulted from such infringement, the aggrieved party may demand that it be remedied pursuant to general regulations.

Rights in personam in the field of creativity, including science, are also entitled to protection as provided for in the provisions of the Copyright Act[38]. Due to the link between the artist and the work, rights in personam in the form of scientific creativity are also protected on the basis of copyright law when they fulfill the prerequisites for recognition as a work[39].

It should be emphasized that despite some social concerns, the freedom of scientific research, including research into human biological samples, is a protected value throughout the entire Polish and European legal systems[40]. Within the meaning of the Constitution, it is protected as human freedom, without subjective limitations.

There is no doubt that conducting scientific research is associated with many social concerns[41]. In terms of research on human biological samples, these mainly concern the rights of donors, patients and participant. Those rights are

37 M. Pazdan, [in:] M. Safjan (ed.), *Prawo cywilne – cześć ogólna, vol. I*, Warszawa 2012, pp. 1258–1260.

38 Ustawa z dnia 4 lutego 1994 r. o prawie autorskim i prawach pokrewnych, Dz.U. 2019, item 1231.

39 A. Wojciechowska, *Czy autorskie dobra osobiste są dobrami osobistymi prawa cywilnego*, "Kwartalnik Prawa Prywatnego" 1994, no. 3, p. 371.

40 Article 13 EU Charter of Fundamental Rights; I. Spigno, *Freedom of Science Research, Max Planck Encyclopedia of Comparative Constitutional Law,* 01.2018, https://oxcon.ouplaw.com/view/10.1093/law-mpeccol/law-mpeccol-e169 [access: 20.08.2019]; J. Rezmer, *Wolność badań naukowych w świetle prawa międzynarodowego,* Toruń 2015.

41 Reports: J. Domaradzki, *Postawy społeczne wobec biobankowania ludzkiego materiału biologicznego*, http://bbmri.pl/pl/elsi/89-raport-postawy-spoleczne-wobec-biobankowania-ludzkiego-materialu-biologicznego and J. Domaradzki, *Genetyzacja społeczna w kontekście biobankowania*, http://bbmri.pl/pl/elsi/88-raport-genetyzacja-spoleczna-w-kontekscie-biobankowania [access: 21.08.2019].

the most import boundary of the freedom of biomedical research and the foundation of biobanking.

5. Rights of participants, donors and patients in biobanking

The Polish and global discussion on biobanks has been focused on the issue of donor rights for years. Interestingly, there are some universal donor rights independent of national legal regulations[42]. Despite the lack of a specific act on biobanking and conducting research on human biological samples, donor rights are the subject of the main legal publications on biobanking in Poland. They are derived from basic human rights and personal rights.

The first of these rights is the right to autonomy[43]. It assumes that consent to transfer a biological sample to a biobank should be independent of consent for any medical service and that it may be withdrawn at any time. It is worth pointing out in this respect that the postulates of Polish donors are far more extensive. Research conducted by J. Pawlikowski[44] clearly shows that donors expect respect for autonomy. There is no acceptance in this respect for a broad formula of consent or replacement consent, and in particular for consent to the use of blank data. Also, due to limitations in the scope of further control and obtaining feedback, 70% of respondents expressed support for coding their data rather than full anonymization[45]. This clearly shows the need for potential donors to be given a guarantee of the greatest possible autonomy in terms of transferred data and samples[46]. This respect for autonomy also assumes that potential donors have an impact on the selection of studies that are conducted on their sample. Postulates in this regard were shaped negatively in terms of subject matter, i.e. as the possibility of stating that some research (e.g. on cloning[47]) should not be conducted on a given sample or data, and subjectively, i.e. that specific entities (e.g. commercial or foreign[48]) will not be able to conduct research using a given sample or data.

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42 A. Janecka-Chabior *Sytuacja prawna biobanków* [in:] E. Kabza, K. Krupa-Lipińska (ed.), *Prawo cywilne w świetle obecnej regulacji i pożądanych zmian,* Toruń 2013, p. 264.

43 D. Krekora-Zając, *The Rights of Donors to Autonomy and Privacy as the Basis for the Functioning of Biobanks in Times of Big Data*, "Studia Iuridica" 2018, no. 73, p. 66.

44 J. Pawlikowski, *Biobankowanie…* p. 192.

45 Ibid., p. 175.

46 D. Mascalzoni, *Zgoda dynamiczna w projekcie Chris Study,* "Studia Iuridica" 2016, no. 73, pp. 43–46.

47 Ibid., p. 152.

48 Ibid., p. 117.

Therefore, recognizing not only the right to autonomy as a lack of compulsion to participate in research, but also as being an active participant in research, has become a new trend[49]. It should be emphasized that respondents have expressed similar demands in both American and European research[50].

The second right, distinguished by K. Łakomiec[51], is the right to privacy and information autonomy. Analyzing the jurisprudence of the Polish Constitutional Tribunal, the author indicates several basic threats related to the functioning of biobanks. First of all, he indicated that the threat to privacy is not only related to the fact of storing data, but also to the fact that a large amount of data about a given individual is combined in the biobank, including health data with identification data. Secondly, he argues that the fact that biobanks store and process data without specifying a time frame may potentially entail greater interference with individual rights. The third and last threat in this regard is data sharing by biobanks. He postulates that in order to reduce interference with the information autonomy of the individual, it is necessary to clearly specify the requirements that these entities must meet in order to use the data. Łakomiec[52] points out that in order to avert these threats, the legislator should introduce a range of constitutional guarantees such as statutorily determined procedural and technical guarantees for the secure processing of personal data; limiting the catalog of data processors to a minimum as dictated by the type of data and the purpose of processing; defining the time frame for data processing; introduction of an effective mechanism for anonymization; introduction of provisions enabling stable financing and maintenance of databases to ensure their smooth functioning in the era of dynamic development of modern technologies and the various types of risk associated with it[53].

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49 J. Domaradzki, J. Pawlikowski, *Public Attitudes toward Biobanking of Human Biological Material for Research Purposes: A Literature Review,* "Public Health" 2019, no. 12, p. 2209.

50 A. Lemke, A.W. Wolf, J. Hebert-Beitne, M.E. Smith, *Public and Biobank Participant Attitudes toward Genetic Research Participation and Data Sharing*, "Public Health Genomics" 2010, no. 13, pp. 368–377; M. Prictor, H.J.A. Teare, J. Kaye, *Equitable Participation in Biobanks: The Risks and Benefits of a "Dynamic Consent" Approach*, Frontiers in Public Health, 05.08.2018, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6133951/pdf/fpubh-06–00253.pdf [access: 21.08.2019]; N.I. Heredia, S. Krasny, L.L. Strong, L. von Hatten, L. Nguyen L., B.M. Reininger, L.H. Mc Neil, M.E. Fernández, *Community Perceptions of Biobanking Participation: A Qualitative Study among Mexican-Americans in Three Texas Cities*, "Public Health Genomics" 2017, no. 20, pp. 46–57.

51 K. Łakomiec, *Biobanki w dobie Big Data z perspektywy prawa konstytucyjnego,* "Studia Iuridica" 2018, no. 73, pp. 105–116.

52 Ibid., p. 115.

53 Verdict of Poloish Constitutional Tribunal of 20 January 2015, K 39/12, "Orzecznictwo Trybunału Konstytucyjnego - seria A" 2015, no. 1, item 2.

An important aspect of the right to privacy in the context of biobanking is protection of donor privacy[54], understood as protection of donor-related information[55]. It consists of the protection of personal data processing, protection against discrimination and the right to be informed (to know[56]) and not to be informed (to ignorance[57]). These rights have been significantly modified[58] by the GDPR[59]. The use of personal data for the purposes of scientific research and biobanking under the GDPR involves the possibility of many restrictions on the rights of the persons from whom the data originates[60]. In particular, it should be noted that the GDPR allows the secondary use of personal data for scientific purposes (without obtaining a new consent), limiting the right to be forgotten and limiting the information obligations of the data controller[61].

The third important problem in the field of biobanking for scientific purposes is the obligation to provide donors with information relevant to their health discovered somewhat accidentally as part of conducted research, so-called incidental findings. According to Art. 9 of the Act on Patient Rights and Patient Ombudsman[62], the patient has the right to obtain all information

54 J. Pawlikowski, *Ochrona prywatności dawców w kontekście biobankowania ludzkiego materiału biologicznego dla celów badań naukowych* [in:] O. Nawrot, A. Wnukiewicz-Kozłowska (ed.), *Temida w dobie rewolucji biotechnologicznej – wybrane problemy bioprawa*, Gdańsk 2015, p. 163.

55 For an overview of European legal regulations on the subject, see D. Krekora-Zając, *Charakter prawny genomu ludzkiego* [in:] A. Bobko, K. Cynk (ed.), *(Gen)etyczna przyszłość człowieka*, Rzeszów 2016, p. 142 et seq.; D. Krekora-Zając, *Prawo do materiału genetycznego człowieka*, Warszawa 2014, p. 53.

56 J. Bovenberg, T. Meulenkamp, E. Smets, S. Gevers, *Biobank Research: reporting Results to Individual Participants*, "European Journal of Health Law" 2009 no. 16, p. 229 et seq.

57 B. M. Knoppers, *The right not to know*, "Journal of Law, Medicine and Ethics" 2014 no. 6, p. 2.

58 Z. Warso, *Przetwarzanie danych osobowych do celów badań naukowych w świetle ogólnego rozporządzanie o ochronie danych osobowych* [in:] A. Białek, M. Wróblewski (ed.), *Wybrane aspekty praw człowieka a bioetyka*, Warszawa 2016, pp. 41–50; D. Krekora-Zając, *Zgoda…*, pp. 51–64.

59 General Data Protection Regulation OJ L 119, 04.05.2016; cor. OJ L 127, 23.5.2018

60 B. Marciniak, P. Topolski, D. Strapagiel, *Anonimizacja w dobie wielkich danych – sytuacja biobanków w kontekście RODO,* "Studia Iuridica" 2018, no. 73, pp. 73–86; A. Mednis, *Ochrona danych genetycznych jako danych osobowych*, "Studia Iuridica" 2018, no. 73, pp. 87–104; S. Penase, A. Dias Pereira, I. De Miguel Berian, P.N. Jiménez, C. Barbosa, T. Sroka, A. Białek, M. Tomasi, T. Chortara, *The EU General Data Protection Regulation: How will it impact the regulation of research biobanks? Setting the legal frame in the Mediterranean and Eastern European area,* Medical Law International, 02.04.2018, p. 11 et seq., http://journals.sagepub.com/doi/abs/10.1177/0968533218765044 [access: 21.07.2019].

61 I. Budin-Ljøsne et al., *Feedback of Individual Genetic Results on Research Participants. Is it Feasible in Europe?*, "Biopreservation and Biobanking" 2016, no. 2, pp. 241–248.

62 Ustawa z dnia 6 listopada 2008 r. o prawach pacjenta i Rzeczniku Praw Pacjenta (Dz.U. 2019, item 1127).

about his health. This is a prerequisite for making an autonomous and informed decision about the choice of therapy. Therefore, a physician who receives any information, including from scientific research, that is relevant to the patient's health is required to disclose it to the patient. In practice, such an obligation can be difficult to implement, because biobanks are not always informed about the discoveries of scientists to whom they provide samples, and these scientists obtain pseudo-anonymized data or even data without any means of identification. However, it is increasingly pointed out that donors are becoming active participants in biobanking (e.g. through co-creation of the principles of biobank operation), and the obligation to provide information on discoveries relevant to donor health should be envisaged as part of each project[63].

The fourth important issue with biobanking is determining the rights to a human biological sample and the rules for transferring it to other research units or scientists. The transfer of samples and data takes place on the basis of a Material Transfer Agreement and a Data Transfer Agreement. These agreements are concluded using standard contracts whose provisions are created by individual biobanks or scientific and medical organizations[64]. They specify not only the rules for submitting the sample or data but also any payment, intellectual property rights to the results of tests carried out with the use of samples, copyrights for the publication of results and the possibility of using the samples or data by the recipient[65].

The last significant problem is determining the legal status of the person from whom a sample is taken[66]. In theory it can be concluded that most human biological samples are collected during medical procedures, and therefore the donor is also a patient and is entitled to all rights under the Act on Patient Rights and Patient Ombudsman[67]. In practice, however, such a solution will not be possible in all cases. Firstly, because the donor will not always be a person seeking health services or using the health services of an entity providing health services or a person performing a medical profession. Not all biobanks must be entities providing health services within the meaning of Art. 2(1)0 of the Act of 15 April 2011 on Medical Activity[68]. Secondly, some biobanks collect human biological samples

63 I. Budin-Ljøsne et al., *Feedback of Individual…*, pp. 241–248.

64 D. Krekora-Zając, *Biobanki* [in:] E. Zielińska, M. Boratyńska, P. Konieczniak (ed.), *Regulacja prawna czynności medycznych,* Warszawa 2019, pp. 145–146.

65 T. Margoni, *The role of material transfer agreements in genetics databases and bio-banks* [in:] G. Pascuzzi (ed.), *Comparative issues in the governance of research biobanks,* Cham 2013, p. 236.

66 D. Krekora-Zając, *The Rights…*, p. 63; Id., *Ludzka próbka biologiczna wykorzystywana dla celów naukowych jako przedmiot prawa cywilnego*, "Studia Prawnicze" 2015, no. 3, pp. 89–134.

67 Id., *Biobanki…* p. 142.

68 Ustawa z dnia 15 kwietnia 2011 r. o działalności leczniczej, Dz.U. 2018, item 2190.

even without the need to violate bodily integrity, such as samples of saliva or urine, and without the involvement of medical personnel. Thirdly, even when the sample was collected during the provision of a health service (e.g. during surgery or blood collection for diagnostic purposes), patient rights do not in fact cover what is most important for biobanking, i.e. its further processing for scientific purposes. In practice, patient rights will not protect samples that are no longer needed for diagnostic or therapeutic processes and can only be classified as medical waste.

6. Conclusions

The lack of legal regulation of biobanks in Poland has become an impulse to develop regulations for the functioning of biobanks based on basic constitutional values related to human rights, and to create rules of conduct based on internationally recognized donor rights. This trend is particularly visible within the standards[69] created by BBMRI[70], in which donors' rights to privacy and autonomy are key issues[71]. In addition to the standards mentioned above, work is underway on the adoption of a code of conduct regarding the processing of personal data by biobanks in Poland[72], where by creating detailed rules for the protection of donor data, a whole system of protection of donor rights at the European level has been created. An undoubted advantage of such approaches to developing regulations is the fact that they are created jointly by lawyers specializing in various fields of law, doctors, quality specialists, sociologists, bioethics, philosophers and representatives of patient organizations. Issues surrounding biobanking are becoming an increasingly important element of legal discourse in both Poland and Europe as a whole.

69 *Quality Standards for Polish Biobanks, Prepared by the Team for Quality Assurance and Management System (QMS) operating within the BBMRI.pl consortium*, K. Ferdyn, J. Gleńska-Olender, K. Zagórska, M. Witoń, I. Uhrynowska-Tyszkiewicz, A. Matera-Witkiewicz (ed.), Wrocław 2018.

70 Those Quality Standards for Polish Biobanks have been accepted for evaluation as European guidelines by BBMRI. ERIC. http://bbmri.pl/pl/qms/84-standardy-jakosci-dla-biobankow-polskich-zaakceptowane-do-ewaluacji-jako-wytyczne-bbmri-eric [access: 13.08.2019].

71 K. Ferdyn, J. Gleńska-Olenader, M. Witoń, K. Zagórska, Ł. Kozera, A. Chróścicka, A. Materia-Witkiewicz, *Quality Management System in the BBMRI.pl Consortium: Status Before the Formation of the Polish Biobanking Network, Biopreservation and Biobanking*, 22.04.2019, https://www.liebertpub.com/doi/full/10.1089/bio.2018.0127 [access: 13.08.2019].

72 https:// bmri.pl/pl/elsi/67-kodeks-postepowania-w-sprawie-przetwarzania-danych-osobowych-dla-celow-badan-naukowych-przez-biobanki-w-polsce [access: 13.08.2019].

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SUMMARY

The paper discusses some interpretative trends in Polish legal doctrine facilitating derivation of the principles of biobank operations in Poland from basic constitutional freedoms and personal rights. Biobanking is a relatively new idea in both Poland and Europe, therefore the considerations begin with a description of the specifics of establishing biobanks in Poland against the background of the development of this idea around the world. Then, the legal basis for conducting scientific research on human biological samples is considered based on the only institution regulated by Polish law related to conducting research on the human body, i.e. the regulation of medical experiments. Due to the inadequacy of the regulation of experiments for conducting research on human biological samples, an attempt is made to elaborate the deliberations of the Polish doctrine regarding the freedom of scientific research and basing the functioning of biobanks on this freedom. However, it is impossible to write about biobanks without considering the rights of donors, therefore the last part of the article shows how representatives of the doctrine of Polish law derive from national law universal rights of donors recognized throughout Europe.

The summary of the article describes attempts to create Polish soft law regulations that are being implemented by European biobank associations.

Keywords: biobank, consent, privacy, data protection, human biological samples, freedom of science, donors right, MTA, DTA, biomedical research