*Dorota Krekora-Zając*
University of Warsaw
Biobanking and BioMolecular resources
Research Infrastructure Poland (BBMRI.Pl)

# THE RIGHTS OF DONORS TO AUTONOMY AND PRIVACY AS THE BASIS FOR THE FUNCTIONING OF BIOBANKS IN TIMES OF BIG DATA[1]

## 1. INTRODUCTION

The development of biobanking for scientific purposes is impossible without social acceptance for the operation of biobanks. This is best shown by the example of the creation of a biobank in the Democratic Republic of Tonga[2] and problems in acquiring donors with which biobank is measured from Egypt[3]. Of course, it can be pointed out that there are still bioresposites that store human biological samples taken without consent and even donor knowledge – without guaranteeing the material from whom the material has been obtained, but it should be clearly stressed out that they have very limited significance for scientific research. The future of science are large and modern biobanks, which collect specific biological samples for the needs of scientific research, i.e. population and clinical biobanks.

The donors' rights to human biological sample are a central problem of biobanking for many years. Many problems which raised in the 1980s are still

[1] The presentation has been prepared as part of the project Sonata 12 n. 2016/23/D/HS5/00411 financed from the resources of National Science Centre, Poland.

[2] G. Palson, *Antropology*, *ant the New Genetics*, Edynburg 2007, p. 103.

[3] W. El-Sayed Abd El-Aal1, N. Fathy Abaas, S. Labib El-Sharkawy (*et al.*), *Biobanking: A challenge facing pathologists in Egypt*, "British Journal of Medicine and Medical Research" 2015, Vol. 13, issue 1, pp. 1–10. At the European Biobank Week (conference held on 13–16 September 2016 in Vienna) A. Abdelhafiz, R. Ali (Using different tools to introduce a biobanking concept for the public in Egypt) indicated that due to social mistrust in relation to biobanks all information programs related to their activities are directed only to medical students (summary of presentation available on http://europebiobankweek.eu/wp-content/themes/offreWP_ebw/images/abstract_book_V5.pdf, accessed: 7.08.2017).

valid and unresolved, such as the problem of informed consent to biobanking, the right to the autonomy of donors[4], the development of genetic research.

Big Data[5] basis created new and previously unknown expectations of donors and participants of biomedical research. The subject of the article will be presenting the challenges for biobanks and their legal regulation in the field of protection of donors' rights[6].

## 2. PROTECTION OF DONORS' RIGHTS WITHOUT A LEGAL BASIS

The basic problem related to the functioning of biobanks and the protection of the donors' rights is the lack of binding legal regulations both in Polish and international law. Traditionally, it was pointed out[7] that their absence creates a great uncertainty regarding the permissible use of human biological samples, which directly translates into social trust in biobanks. According to J. Pawlikowski's research, there is quite a large acceptance in Poland of biobanking human biological samples for scientific purposes, although it is significantly limited by the uncertainty[8] as to the powers that biobanks have in relation to the further transfer of samples, export them abroad and commercialization of research[9].

---

[4] B. M. Knoppers, C. Laberge, *DNA sampling and informed consent*, "Canadian Medical Association Journal" 1989, Vol. 140, issue 9, p. 1025.

[5] S. Paul, A. Gade, S. Malipeddi, *The State of Cloud-Based Biospecimen and Biobank Data Management Tools*, "Biopresernation and Biobanking" 2017, Vol. 15, issue 2, p. 170.

[6] The article was created as a result of the project financed by the National Science Centre Sonata No. 2016/23/D/HS5/00411 Contracts for biobanking human biological samples for scientific purposes.

[7] This problem was already signalled by the author in the publication *On the need to regulate biobanks* published in the "State and Law" 2012, Vol. 5, since then legislative work in the Ministry of Science and Higher Education and in the Ministry of Health has continued. As a result of the work of ministerial teams, draft laws and reports were created, which were never published or directed to further legislative work.

[8] Lack of legal regulation means that this uncertainty also applies to understanding the meaning of individual concepts by those involved in the biobanking process, such as doctors, IT specialists, lawyers, ethicists, biologists or laboratory diagnostics. Research conducted in a Danish biobank showed that the employees of this biobank, depending on their education and their function, used a completely different meaning of such basic concepts as data, information or sample (H. Ellis, M. B. Joshi, A. J. Lynn (*et al.*), *Consensus-Driven Development of a Terminology for Biobankig*, *the Duke Experience*, "Biopreservation and Biobanking" 2017, Vol. 15, issue 2, p. 131). In this situation, it is impossible to provide precise information to donors, which ultimately makes it impossible to obtain informed consent.

[9] J. Pawlikowski, *Biobankowanie ludzkiego materiału biologicznego dla celów badań naukowych – aspekty organizacyjne*, *etyczne*, *prawne i społeczne*, Lublin 2013, p. 119.

Currently, Polish biobanks operate without proper legal regulations, creating their own standards of conduct based largely on European law and soft law regulations[10] created by international organizations as well as guidelines and recommendations of organizations associating biobanks such as BBMRI-ERIC (these are binding for biobanks members of the BBMRI.Pl[11]) or ISBER (International Society of Biological and Enviromental Repositories)[12]. Some Polish biobanks also harmonize their standards for dealing with donors as part of cooperation with biobanks from other countries, such as UKBiobank[13].

In theory, it can be concluded that the majority of human biological samples were collected during medical procedures, and therefore the donor becomes a patient and is entitled to all rights under the Patient Rights and Patient Rights Ombudsman Act. In practice, however, such a solution will be possible in a few cases only. Firstly, because not always the donor will be a person applying for health services or using health services provided by the entity providing health services or a person performing a medical profession[14]. Not all biobanks must be entities providing health services within the meaning of art. 2 point 10 of the Act of 15 April 2011 On Medical Activities[15]. Secondly, a some of the biobanks collects human biological samples even without the need to violate bodily integrity, e.g., saliva or urine samples, and without the involvement of medical personnel. Thirdly, even when the sample was collected during a health service (e.g. during surgery or blood collection for diagnostic purposes), patient rights do not include what is most important for biobanking, i.e. its further processing for scientific purposes. In practice, patient's rights will not protect those samples that are no

[10] In October 2009, the OECD Council adopted a Recommendation on Human Biobanks and Genetic Research Databases; WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks Adopted by the 53rd WMA General Assembly, Washington, DC, USA, October 2002 and revised by the 67th WMA General Assembly, Taipei, Taiwan, October 2016; Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, European Treaty Series No. 164; Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, Strasburg 25.01.2005, European Treaty Series No. 195.

[11] M. Witoń, D. Stapagiel, J. Gleńska-Olender (*et al.*), *Organization of BBMRI.pl: The Polish Biobank Network*, "Biopreservation and Biobanking" 2017, Vol. 15, issue 3, p. 269.

[12] C. A. Allocca, M. J. Bledsoe, K. Furuta (*et al.*), *ISO/TC276/WG2 Biobanks and Bioresources: Draft International Standard is now available for comment*, "Biopreservation and Biobanking" 2017, Vol. 15, issue 4, pp. 399–401.

[13] Such a cooperation agreement was also signed by representatives of Polish biobanks.

[14] Definition of the concept of patient art. 3 point 4 of the Act on Patient Rights and Patient Ombudsman of November 6, 2008 (Dz.U. z 2017 r., poz. 1318).

[15] Dz.U. z 2014 r., poz. 1638, z późn. zm.

longer needed for the diagnostic or therapeutic process, and can only be classified as medical waste[16].

However, such a legal situation results that the whole legally binding legal regulation is in the contractual node concluded between the biobank and the donor and, in practice, this contract takes the form of unilateral, often fairly general information provided by the biobank and signing the consent form for the biobanking. Therefore, donors are not always informed about the transfer of samples and data to other establishments, including commercial ones. Therefore, all rights granted to donors by soft law acts can only be considered as habits that affect the extent of due diligence that a biobank should have to a donor. In addition, according to the standards determined by, for example, according to § 3.1. OECD Guidelines on Human biobanks and Genetic Research Databases using human biological samples is possible also without the consent of the donor, if the competent bioethics committee agrees. In this respect, the consent of the bioethics commission replaces the consent of the donor and undoubtedly prevents the donor from being able to claim his rights.

Therefore, it is difficult to create legally binding biobanks regulations regarding donors. In this total chaos connected with donor rights, a new regulation of the General Data Protection Regulation should be imposed (hereinafter: GDPR)[17]. It introduces two legal regimes – one very restrictive, assuming that collecting the so-called Sensitive personal data is possible only after obtaining the consent of the person from whom the data come from and the second (Article 9 of the GDPR) enabling to ease the rigors of the GDPR for data processing for scientific purposes in the case of legal regulations guaranteeing protection of the rights and freedom of the data subject. This means that in the absence of adoption by the legislator of Polish regulations guaranteeing the rights of donors or participants of biomedical research, their data can be processed only in the first more restrictive regime. In practice, due to the scale of the collected samples and difficulties in contact with donors, the biobanks will face the need to terminate the activity to or anonymize data of all donors. Both solutions are extremely destructive to the development of science, but most of all they still do not guarantee donors any rights.

[16] It is also problematic when a given sample becomes a medical waste and subject to absolute utilization. This is definitely a topic for separate considerations.

[17] Regulation (Eu) 2016/679 of the European Parliament and of the Council Of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Dz.Urz. UE L 119 z 4.05.2016, p. 1).

## 3. RIGHT TO SAMPLE AND RIGHT TO DATA PROTECTION AND INTERNATIONAL BIOMEDICAL RESEARCH

Pointing to the need to undertake legislative work in the field of protection of donors' rights, it should be noted that traditionally the rights of donors are divided into rights related to a biological sample and personal data related to it. Comparative law research presented by Heidi Beate Bentzen[18] at the Europe Biobank Week conference, shows that in Eastern European countries one identifies the protection of the rights of the donor with the protection of personal data, while in Western Europe, data protection from the protection of the sample is clearly distinguished.

Perceiving the protection of rights resulting from the processing of personal data and biological material is a search for a balance between the protection of the donors' privacy and the possibility of conducting scientific research. The processes of globalization, so important for the development of science and thus also biobanking, have made the basis for modern biomedical research the mutual sharing of genetic data between scientific and medical centers (this phenomenon is known as Genomic Data Sharing)[19] and the creation of large international research consortia managing tens of millions samples[20].

Donors' rights must therefore be global in nature, regardless of the country from which the donor comes. Donor problems are also universal in nature.

The proof of such an approach at the European level is undoubtedly the GDPR processing of data for scientific purposes. The Regulation creates completely new mechanisms to control the processing of personal data, and therefore also in a completely different way shapes the entitlement of donors, creating a great uncertainty, which I wrote earlier, regarding the further functioning of biobanks. A solution in this respect is created by Article 40 GDPR, according to which it is possible to create codes of conduct which, once approved by the competent inspection bodies and published by the Commission, become binding. Such a code is already created for the processing of data for scientific purposes and is intended to guarantee donors specific rights with regard to the processing of their data[21].

---

[18] H. B. Bentzen, *Human Biological Samples versus Personal Data*; more information about the conference available: http://europebiobankweek.eu (accessed: 16.01.2018).

[19] M. Shabani, E. S. Dove, M. Murtagh (*et al.*), *Oversight of genomic data sharing: What roles of ethics and Data Access Committees?*, "Biopreservation and Biobankig" 2017, Vol. 15, issue 5, p. 472.

[20] P. Holub, M. Swetz, R. Reihs (*et al.*), *BBMRI-ERIC Directory: 515 Biobanks with over 60 Milion Biological Samples*, "Biopreservation and Biobankig" 2016, Vol. 14, issue 6, p. 559.

[21] The initiator of the creation of the code of conduct is BBMRI-ERIC, according to the work plan, it is to be made public at the beginning of 2018. Polish representatives are involved in

The second problem, i.e. the right to a biological sample, has been the subject of many judgments of the American courts, as in the case of Morra[22], Canavan and Catalona[23]. Over the years, it seemed that both European and American law strengthened the principle derived from the transplant law that donors do not have the right to obtain financial benefits in exchange for transferred tissues and cells and that they do not have any rights to a biological sample. Currently, it should be pointed out that new publications emerging from patient movements suggesting[24] the need to clearly determine the donor's rights to the sample. M. Bledsoe[25] using the term biorights in relation to such postulates, indicating that it would be necessary to answer the following questions about:

1) the rights and obligations of donors to samples and the extent of their participation in profits,

2) the right to control the use of samples for research purposes,

3) and the right balance between the right to autonomy and the rights of the community in the field of research.

## 4. INFORMED CONSENT

The third fundamental problem with regard to donors' rights is the legal nature and scope of consent given by donors[26]. There is no doubt that the dominant way to protect the rights of donors is to base the protection model on the informed consent. In accordance with point 12 of the Tajpei Declaration, consent is valid only if it was preceded by information on: the purpose of the medical database or biobank; the risks and burdens associated with the collection, storage and use of data and material; the type of data and material to be collected; procedures for the return of results, including accidentally detected health information; rules for

---

this work. More on this topic http://www.bbmri-eric.eu/news-events/code-of-conduct-for-using-personal-data-in-health-research/ (accessed: 16.01.2018).

[22] *Moore v. Regents of the University of California* (1990) 51 Cal. 3d 120 (271 Cal. Rptr. 146, 793 P.2d 479), http://law.justia.com/cases/california/cal3d/51/120.html (accessed: 16.01.2018).

[23] *Washington University v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006), www.circare.org/lex/03cv01065_opinion.pdf (accessed: 16.01.2018).

[24] T. Caulfield, B. Murdoch, *Genes*, *cells*, *and biobanks: Yes*, *there's still a consent problem*, "PLOS Biology" July 25, 2017, available http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.2002654 (accessed: 16.01.2018).

[25] M. J. Bledson, *Ethical Legal and Social Issues of Biobanking: Past*, *Present*, *and Future*, "Biopreservation and Biobanking" 2017, Vol. 15, issue 2, p. 145.

[26] J. Pawlikowski, *Biobankowanie ludzkiego materiłu biologicznego…*, s. 171.

access to medical databases or biobanks; how privacy is protected; that if the data and material become completely anonymous, the donor will not be able to find out what is happening with his data or material and that he will not be able to withdraw his consent; the fundamental rights and guarantees laid down in this Declaration; commercial use and distribution of benefits, intellectual property issues and the transfer of data or material to other institutions or third countries, if applicable. In addition, the Declaration constructs two more rights in this respect, i.e. the right to withdraw consent with effect for the future (point 15) and the right to receive information on the use of data (paragraph 14). This right to information has also become a central mechanism guaranteeing the protection of donors' rights in the OECD Guidelines, such as information (point 4): on acceptable re-contact; on situations in which researchers will have access to non-coded personal data when the biobank will be obliged to make available biological material or data to third parties for non-testing purposes, the right to withdraw consent, about commercial products that may be generated as a result of testing on human biological samples or data and benefits that the participant can relate to.

It is still emphasized that the problem of consent for biobanking may decide about "to be or not to be" biobanks. Meanwhile, it seems that long-lasting discussions on the international forum regarding the definition of informed consent for biobanking have shown the need to create new protective mechanisms[27]. In contrast to the concept of informed consent, understood as consent to biobanking for a specific research objective in an increasing number of countries, the concept of broad consent is adopted[28].

As the adopted text of the GDPR on the European level shows, there is also acceptance that the use of not all biological samples may be based on the conscious consent of the donor. Pursuant to Article 5 (1b) GDPR, data collected for another purpose are processed in accordance with the purpose if they are processed for scientific purposes. In practice, it seems that particularly in the area of protection of the rights of donors associated with personal data, relying only on informed consent may be insufficient. In the days of Big Data and the merging of new data registers, it is difficult to clearly indicate at what stage consent should be obtained, since all processing should be covered. However, passing samples and using them in many research projects in different countries makes the consent only a formal way of protection.

---

[27] J. Pawlikowski, *Dyskusja wokół koncepcji świadomej zgody w kontekście badań naukowych z użyciem ludzkiego materiału biologicznego*, "Diametros" 2015, No. 44, p. 104.

[28] M. A. Rothstein, B. M. Knoppers, H. L. Harell, *Comparative approaches to biobanks and privacy*, "Journal of Law, Medicine and Ethics" 2016, Vol. 44, issue 1, pp. 3–6.

## 5. THE RIGHT TO AUTONOMY IS NOT JUST INFORMED CONSENT

It is worth pointing out in this respect that the postulates of donors in Poland are far farther. It is clear from the research conducted by J. Pawlikowski[29] 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. Due to restrictions on further control and obtaining feedback, 70% of respondents were in favor of coding their data, not for full anonymisation[30]. This clearly shows the need for potential donors to guarantee them the highest level of autonomy regarding the data and samples transferred. This respect of autonomy also presupposes that potential donors influence the choice of research that is conducted on their sample. The postulates in this respect have been shaped negatively in terms of the subject, i.e. the possibility that some research (e.g. cloning[31]) should not be carried out on a given sample or data and subjectively, ie that specific entities (e.g. commercial or foreign[32]) will not be able to run tests using a given sample or data. A new trend, therefore, was the recognition not only of the right to autonomy as a lack of coercion to participate in research, but also as an active participant in research[33]. It should be emphasized that similar postulates were expressed by respondents in both American[34] and European[35] studies.

## 6. THE RIGHT TO FEEDBACK INFORMATION ABOUT INCIDENTALS FINDINGS

The right to information has become the basis of medical law and protection of patients' rights as well as consumer law. Traditionally, therefore, it is identi-

[29] J. Pawlikowski, *Biobankowanie ludzkiego materiału biologicznego*…, p. 192.

[30] *Ibidem*, p. 175.

[31] *Ibidem*, p. 152.

[32] *Ibidem*, p. 117.

[33] M. Shabani, L. Bezuidenhout, P. Borry, *Attitudes of research participants and the general public towards genomic data sharing: a systematic literature review*, "Expert review of molecular diagnostics" 2014, Vol. 14, issue 8, pp. 1053– 1065.

[34] J. Murphy, J. Scott, D. Kaufman (*et al.*), *Public Perspectives on Informed Consent for Biobanking*, "American journal of public health" 2009, Vol. 99, issue 12, pp. 2128–234.

[35] G. Gaskell, S. Stares, A. Allansdottir (*et al.*), *Europeans and Biotechnology in 2010. Winds of change? A report to the European Commission's Directorate-General for Research*, Brussels 2010, p. 50.

fied with information that is received by the subject who should be protected (patient, consumer) so that he can make an informed consent to a medical procedure or contract. In the field of biobanking, this obligation is increasingly understood much more honestly, i.e. as an obligation to provide information to donors after obtaining consent in the course of conducted scientific research. In recent years there have been many voices of patient organizations indicating the need to provide donors with information that has been obtained as part of their research and analysis on their biological samples and biomedical data. Under the CHIP Me program[36] in 2014, analyzes were carried out from 22 European countries, which clearly showed[37] that action at European level is necessary in terms of the necessity to introduce the obligation to provide information of importance to the patient in relation to his health.

The postulation of such an obligation results from the very idea of biobanking, which is based on the honorary donation of biological samples associated with the particular trust that biobanks should enjoy. So if donors donate their biological material without a gratuity, it is natural that they should receive some additional medical information (in practice, donors most often receive morphological results or cholesterol levels). However, the right to obtain information about the so-called incidental findings is definitely more difficult for biobanks due to legal, economic and organizational constraints.

The question arises whether in the absence of express consent to the transfer of such information will not be a violation of the right to autonomy, of which the right to non-being is an integral part. The Universal Declaration on Human Genome and Human Rights directly establishes the human right to abandon all research information, indicating that „The right of every person to decide whether he wants to be informed about the results of genetic testing and the resulting consequences must be respected"[38]. This provision is an expression of the awareness of the nature of the results of such research. It should be remembered that they do not always have to indicate a disease, but only indicate the possibility of its occurrence in an unspecified future. Then such information could only constitute an unnecessary psychological burden for the patient, especially in a situation where for some reasons it is not possible to apply preventive measures.

First of all, the right to information and to non-informed notifications also follows directly from the bioethical convention. According to the wording of Article 10 point 2 everyone has the right to read all the information collected about their

[36] COST Action CHIP ME IS 1303, Citizen's Health through public-private Initiatives: public health, Market and Ethical perspective, European Commission, Brussels, Belgium.

[37] I. Budin-Ljøsne, D. Mascalzoni, S. Soini (*et al.*), *Feedback of Individual Genetic Results to Research Participants: Is It Feasible in Europe?*, "Biopreservation and Biobanking" 2016, Vol. 14, issue 3, pp. 241–248.

[38] Art. 5C Universal Declaration on the Human Genome and Human Rights 1997.

health. The bioethical convention also indicates the need to respect the wishes of a person who does not want to read this information. It should be noted, however, that the bioethical convention allows the possibility of limiting these rights by national legislation. Similarly, in accordance with Recommendation No. 10, the patient's right to knowledge and ignorance should be recognized and professional mechanisms should be introduced to ensure that it is respected. In the context of genetic research involving the provision of information, counseling, informed consent procedures and information on research results, practices should be created to meet these needs[39]. Also, the Additional Protocol to the Bioethical Convention on genetic testing for health purposes recognizes the right of every person to obtain information resulting from genetic tests, as well as expressing the wish of not being informed about them. However, it allows the possibility of limiting these rights due to the good of that person[40]. In addition, the Protocol indicates that everyone has the right to respect for their privacy in the context of genetic testing results.

Secondly, the question arises who would assess whether a given discovery is so significant and reliable for a given person that it already results in an information obligation.

Thirdly, would the biobank also be responsible for the lack of information provided, which he would not be informed by the researchers himself.

Fourthly, the question arises to whom this information should be transmitted, whether directly to the donor or his doctor. Undoubtedly, the introduction of such an obligation will involve the need to include their costs in research projects.

Such a right is postulated both in the Declaration of Taipei and the OECD Guidelines. In addition, it seems that in order to make a decision about further participation in the study, take therapeutic and diagnostic measures, information about the results of research and further negotiations is also necessary. According to Article 26 of the Additional Protocol to the Bioethical Convention on Genetic Testing for Health Purposes, participants should be notified of all information collected about their health. Also, according to the Declaration on human genetic data, no one should be deprived of access to their data in any case[41].

---

[39] E. McNally, A. Cambon-Thomsen, C. Brazell (*et al.*), *25 recommendations on the ethical, legal and social implications of genetic testing*, Bruksela 2004, p. 15.

[40] Art. 16 Additional Protocol to the Convention on Human Rights and Biomedicine, concerning genetic testing for health purposes Strasburg 27.11.2008, European Treaty Series No. 203.

[41] Art. 13 UNESCO International Declaration on Human Genetic Data, available http://portal.unesco.org/en/ev.phpURL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=201.html (accessed: 16.01.2018).

## 7. CONCLUSIONS

In conclusion, it should be pointed out that since the beginning of the creation of biobanks, it was in vain to look for legal guarantees of the basic rights of donors. In Poland, the legislator did not decide to introduce to the legal system regulation on biobanking or biomedical research. The lack of constituted law meant that postulates of donors of human biological samples could only be implemented at the level of not legally binding declarations or recommendations. This resulted in the fact that all donor rights were dependent on the will of the biobank, which provided certain information to the donor or not and on the control of bioethical commissions in this regard. Thus, in relation to such important rights as the right to autonomy or privacy, it is created a system separate from the Polish law and Polish judiciary. On the one hand, the biobanks functioned in a state of legal uncertainty, and on the other hand, the donors did not have guaranteed rights. The change of this situation is enforced by the GDPR, which by creating legally binding and quite restrictive requirements for the processing of personal data also for scientific purposes requires the introduction of principles of protection of the rights of donors. Departure from recognizing that only signing a consent form or obtaining the approval of the bioethical commission is a condition for the legality of the functioning of biobanks should be assessed positively. As shown by the experience of UKBiobank, an important element of conducting research is returning to the donor for new research, data and thus making it an important participant in the research. In times of combining medical records, international data exchange and samples, the right to the autonomy and privacy of the donor takes on a new meaning. Biobank management of Big Data data basis means that there are much more real threats to the violation of donor rights and therefore require the creation of harmonized legal solutions. Modern technologies allow today to communicate with donors more easily (a good example is the use of the dynamic consent model presented in the Deborah Mascalzoni article) and show new possibilities that are unknown at the stage of sample collection. Finally, it should be pointed out that there is a clear and urgent need to undertake legislative work that guarantees donors the right to autonomy, information on the use of their biological material and accidental findings relevant to the health of the donor (incidental findings).

## BIBLIOGRAFIA

Allocca C. A., Bledsoe M. J., Furuta K. (*et al.*), *ISO/TC276/WG2 Biobanks and Bioresources: Draft International Standard is now available for comment*, "Biopreservation and Biobanking" 2017, Vol. 15, issue 4

Bentzen H. B., *Human Biological Samples versus Personal Data*; more information about the conference available http://europebiobankweek.eu (accessed: 16.01.2018)

Bledson M. J., *Ethical Legal and Social Issues of Biobanking: Past*, *Present*, *and Future*, "Biopreservation and Biobanking" 2017, Vol. 15, issue 2

Budin-Ljøsne I., Mascalzoni D., Soini S. (*et al.*), *Feedback of Individual Genetic Results to Research Participants: Is It Feasible in Europe?*, "Biopreservation and Biobanking" 2016, Vol. 14, issue 3

Caulfield T., Murdoch B., *Genes*, *cells*, *and biobanks: Yes*, *there's still a consent problem*, "PLOS Biology" July 25, 2017, available http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.2002654 (accessed: 16.01.2018)

Ellis H., Joshi M. B., Lynn A. J. (*et al.*), *Consensus-Driven Development of a Terminology for Biobankig*, *the Duke Experience*, "Biopreservation and Biobanking" 2017, Vol. 15, issue 2

El-Sayed Abd El-Aal1 W., Fathy Abaas N., Labib El-Sharkawy S. (*et al.*), *Biobanking: A challenge facing pathologists in Egypt*, "British Journal of Medicine and Medical Research" 2015, Vol. 13, issue 1

Gaskell G., Stares S., Allansdottir A. (*et al.*), *Europeans and Biotechnology in 2010. Winds of change? A report to the European Commission's Directorate-General for Research*, Brussels 2010

Holub P., Swetz M., Reihs R. (*et al.*), *BBMRI-ERIC Directory: 515 Biobanks with over 60 Milion Biological Samples*, "Biopreservation and Biobankig" 2016, Vol. 14, issue 6

Knoppers B. M., Laberge C., *DNA sampling and informed consent*, "Canadian Medical Association Journal" 1989, Vol. 140, issue 9

McNally E., Cambon-Thomsen A., Brazell C. (*et al.*), *25 recommendations on the ethical*, *legal and social implications of genetic testing*, Brussels 2004

Murphy J., Scott J., Kaufman D. (*et al.*), *Public Perspectives on Informed Consent for Biobanking*, "American journal of public health" 2009, Vol. 99, issue 12

Palson G., *Antropology*, *ant the New Genetics*, Edynburg 2007

Paul S., Gade A., Malipeddi S., *The State of Cloud-Based Biospecimen and Biobank Data Management Tools*, "Biopresernation and Biobanking" 2017, Vol. 15, issue 2

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

Pawlikowski J., *Dyskusja wokół koncepcji świadomej zgody w kontekście badań naukowych z użyciem ludzkiego materiału biologicznego*, "Diametros" 2015, No. 44

Rothstein M. A., Knoppers B. M., Harell H. L., *Comparative approaches to biobanks and privacy*, "Journal of Law, Medicine and Ethics" 2016, Vol. 44, issue 1

Shabani M., Bezuidenhout L., Borry P., *Attitudes of research participants and the general public towards genomic data sharing: a systematic literature review*, "Expert review of molecular diagnostics" 2014, Vol. 14, issue 8

Shabani M., Dove E. S., Murtagh M. (*et al.*), *Oversight of genomic data sharing: What roles of ethics and Data Access Committees?*, "Biopreservation and Biobankig" 2017, Vol. 15, issue 5

Witoń M., Stapagiel D., Gleńska-Olender J. (*et al.*), *Organization of BBMRI.pl: The Polish Biobank Network*, "Biopreservation and Biobanking" 2017, Vol. 15, issue 3

## THE RIGHTS OF DONORS TO AUTONOMY AND PRIVACY AS THE BASIS FOR THE FUNCTIONING OF BIOBANKS IN TIMES OF BIG DATA

### Summary

The subject of the article is the analysis of the rights of donors donating their biological samples to biobanks in the 21st century. Issues regarding donor rights have been analyzed since the 1980s, however, changing times, creating Big Data databases as well as evolving legal awareness of donors meant that today the role of donors in the biobanking process should be perceived differently. Donors become active subjects of scientific research which is connected with the need to answer questions about the obligations to inform them about the results of scientific research conducted on their samples or incidental findings. Likewise, the combination of data registers and the creation of Big Data basis require the re-thinking of terms such as the protection of personal data of donors or the anonymisation of their data. These issues are imposed by negligence or complete lack of legal regulation of the biobanking, which makes the legal protection of the rights of donors dependent on the will of a particular biobank. All these phenomena result in the necessity of new approaches to the rights of donors and their inclusion in the future legal regulation.

### KEYWORDS

biobanks, donors, consent, biomedical research, information, human biological sample, personal data, GDPR

### SŁOWA KLUCZOWE

biobanki, dawcy, zgoda, badania biomedyczne, informacje, ludzka próbka biologiczna, dane osobowe, RODO