Studia Iuridica 95
ISSN 0137-4346; e-ISSN 2544-3135

DOI: https://doi.org/10.31338/2544-3135.si.2022-95.13

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PHYSICIAN SCIENTIST: CLASH OF PATIENT RIGHTS AND PRINCIPLES OF CONDUCTING RESEARCH

Abstract

Conducting scientific research, learning about the etiology of diseases, and searching for new methods of treatment are undoubtedly the basis of medicine. For centuries, a doctor has been a person who not only treated people, but also conducted scientific research aimed at deepening the knowledge about man. Due to the development of genetics, the pharmaceutical industry, and biobanks, this research has become mass and sometimes it is only human biological samples that are sufficient to carry it out. All this, undoubtedly, enables faster development of science, but puts a doctor in an extremely difficult situation of playing two roles, i.e. treating the patient and conducting scientific research using one's biological material. In medical law, it has been emphasized for years that the basis of the relationship between a doctor and a patient is a special type of trust, which is systemically protected both by national and international legislature. The doctor is, therefore, obliged to act for the benefit of the patient. There is no doubt, however, that when conducting scientific research, a doctor sometimes faces the rivalry of patient rights, including the right to privacy and the right to freedom to conduct research. Both European and national lawmakers seem to notice these problems only partially, and only partially regulate the issue in question in both medical and personal data protection law. The subject of the reported research was analysis of the European and Polish law in terms of determining the extent to which this conflict of interests affects the patient's rights and the doctor's duties. In addition, the subject of analysis was to determine whether the person who gave a biological sample to the doctor to conduct research on it is always

a patient and what consequences for the doctor's legal liability this research on human biological samples has.

KEYWORDS

doctor's responsibility, patient rights, biobank, research on human biological material, consent, freedom of science, trust

SŁOWA KLUCZOWE

odpowiedzialność lekarza, prawa pacjenta, badania na ludzkim materiale biologicznym, zgoda, wolność nauki, zaufanie

1. INTRODUCTION

For centuries, people have been trying to better understand principles governing the human body in order to cure and prevent diseases affecting humanity. Therefore, physicians have become ones who conduct such research. A new group of physician scientists was created, whose aim was not only to treat patients, but to conduct scientific research that could serve future generations.

The development of medical sciences would not be possible without research on human biological samples and use of medical data. Biobanks are established to gather the large numbers of human biological samples and transmit them to the researchers all over Europe. The legal nature of biological samples is being increasingly detached from the donor becoming the subject of their *sui generis* rights.

The aim of the article[1] is to show the complexity of the legal and ethical situation of such physicians scientists conducting research on human biological samples and their responsibility to patients. The medical research on a human being as such has been deliberately excluded from the scope of the study, as they are the subject of separate bioethical and legal standards.

[1] This paper has been prepared as part of the project Sonata 12 No. 2016/23/D/HS5/00411 financed from the resources of the National Science Centre, Poland.

2. BIOMEDICAL RESEARCH IN THE 21ST CENTURY AS A CHALLENGE FOR PHYSICIAN SCIENTIST

The 21st century can be regarded prime time for biomedical research on human biological samples[2]. These studies contribute to the understanding of the etiology of many population diseases, such as cancer and diabetes, as well as genetically determined conditions. Thanks to the results presented by scientists, new drugs and treatment methods are created. Nevertheless, sometimes biomedical research raise ethical doubts.

The disgraceful card in history has been recorded by biomedical research on people during World War II. It showed how many abuses and dangers for an individual can be carried out, and it gave an impulse for adoption of basic ethical and legal norms for conducting scientific research on a human being. Adopted were, among others, the Nuremberg Code[3], the Universal Declaration of Human Rights[4], and the Oviedo Convention[5]. The principles expressed in both the Code and the declarations are aimed at protecting people against damage to life and health associated with research on a living person, not on human biological samples. This need for protection also results from the national laws on medical experiments.

The next breakthrough was the year 2000 and the sequencing of the human genome – the new era of conducting biomedical research has begun. It turned out that many studies can be conducted not on a human body, but on biological material taken from it – which seems to be significantly limited by the possibility of threat to the rights of individuals. Therefore, when conducting research on samples, there is no indication of the traditional risks associated with human research, such as the induction of individual health distress or loss of life. However, in practice research on human biological samples has created new threats and ethical dilemmas. They are related to several factors.

Firstly, conducting reliable research on human biological samples requires collection of many thousands of samples (it is often indicated that even several hundred thousand), so in the case of an improper collection there is a much larger number of injured entities.

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[2] F. Karimi-Busheri, A. Rasouli-Nia, *Biobanking in the 21st century*, Springer 2015, No. 2.

[3] The Nuremberg Code (1947), (in:) A. Mitscherlich, F. Mielke, *Doctors of infamy: The story of the Nazi medical crimes*. New York 1949, pp. xxiii–xxv.

[4] The Declaration was proclaimed by the United Nations General Assembly in Paris on 10 December 1948 (General Assembly resolution 217 A) as a common standard of achievements for all peoples and all nations.

[5] The 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 (ETS No. 164).

Secondly, collecting such a large number of samples for just one study is too expensive and time-consuming. Therefore, it is necessary to biobank these samples, and therefore to transfer them to professional storage entities, which will make them accessible to scientists around the world. Often, therefore, the physician who collects a sample loses the actual control over it by passing it on to the biobank, which transfers it to an unrecognized number of scientists. The idea of biobanking has been recognised by the Time Magazine[6] as one of the leading ideas which may change the world. It is estimated that the value of the biobank market in 2022 could reach USD 2.69 billion[7]. Thanks to the existence of biobanks of human tissues, it is possible to carry out scientific research based on a very large number of samples which would otherwise not be available to scientists. Without biobanks, the development of medicine, pharmacy or genetics would be impossible. The postulates of scientists, who demanded sharing patient's genetic and biomedical data[8], led to the idea of establishing a responsible genomic data sharing center, and the researchers focused their attention on the ethical and legal issues, such as as the consent, privacy, and confidentiality of individuals, families, and communities[9].

Thirdly, in practice, the data contained in these samples will be subject to coding or anonymisation and therefore the natural relationship between the physician conducting the research and the persons from whom the sample originates will be discontinued.

Fourthly, research on human biological samples is carried out not only by physicians but also by other biological scientists, who are not legally obliged to comply with the legal standards for physicians. Therefore, two important questions arise, i.e. who will be responsible and on what terms for the violation of the rights of persons from whom the samples originate and what are the obligations of those who perform research on the donor?

Fifthly, a sample at a certain stage can become commercialized. The HeLa cells are an example of such commercialization. These cells were the first human cells able to divide and multiply outside the human body. They have been used in more than 50 thousand studies on, among others, leukemia, Parkinson's disease

[6] A. Park, *10 ideas changing the world right now: Biobanks*, "Time Magazine" March 2009, http://content.time.com/time/specials/packages/article/0,28804,1884779_1884782_1884766,00.html (accessed 1.01.2018).

[7] The report "Biobanking market by product and service (equipment, consumables, services, software), sample type (blood products, human tissues, cell lines, nucleic acids), application (regenerative medicine, life science, clinical research) – Global Forecast to 2022", https://www.marketsandmarkets.com/PressReleases/biobanking-devices.asp (accessed 1.01.2018).

[8] C. Allen, T. Joly, P.G. Moreno, *Data sharing, biobanks and informed consent: A research paradox*, "McGill Journal of Law and Health" 2013, No. 1, pp. 89–91.

[9] M. Shabani, E.S. Dove, M. Murtag, B.M. Knoppers, P. Borry, *Oversight of genomic data sharing: What roles for ethics and data access committees?*, "Biopreservation and Biobanking" 2017, No. 5, p. 469.

or AIDS. They were also used for research on chemotherapy, gene mapping, *in vitro* fertilization or cloning. It is indicated that thanks to these cells a multimillion-dollar market for the sale of human biological material was created, and the person from whom these cells came from, never participated in profits from it[10].

Sixthly, as a consequence of this process completely different legal standards of data protection apply to patients whose biological material is transferred for scientific purposes and to those who donate their biological samples for scientific purposes only. The subject of the paper will be the presentation of these standards and an indication of their inconsistency.

This dichotomous division is visible not only in Polish regulations but also, and perhaps above all, in European regulations. Natural questions arise about the effects of such differences in the regulations. What will be the liability of the physician who receives a sample from the patient during the course of therapy and uses it to carry out scientific research without the patient's consent? When can a patient be harmed by using his samples and data for scientific purposes? These questions have been the subject of numerous US and Australian court rulings, including most famous Moor case[11]. The entry into force of the EU Data Protection Regulations[12] as well as the Declaration of Helsinki[13] introduced completely new rules on the possibility of using personal data and human biological samples, and force new conclusions to emerge.

3. TRUST FOR THE RESEARCHER AND TRUST FOR THE PHYSICIAN

The basis for treatment and for research on human biological samples is created by a special type of trust[14].

In the first case, there is the patient's trust for the physician to whom they provide all information about their health, addictions, habits, and ailments. It is possi-

[10] D.A. Alford, *HeLa cells and unjust enrichment in the human body*, "Annals of Health Law" 2012 special edition, No. 1, p. 224.

[11] Moore v. Regents of University of California (1990) 51 Cal. 3d 120 [271 Cal. Rptr. 146, 793 P.2d 479].

[12] 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) OJ L 119, 4.5.2016, p. 1–88.

[13] WMA Declaration Of Helsinki – Ethical principles for medical research involving human subjects. Adopted by the 18th WMA General Assembly, Helsinki, 9 July 2018.

[14] A. Kerasidou, *Trust me, I'm a researcher!: The role of trust in biomedical research*, "Medicine, Health Care and Philosophy" 2017, No. 1, p. 43 *et seqq.*

ble only if the patient is sure that the information provided will not be disclosed[15]. The patient gives this information because he trusts that the physician (physician is trustworthy[16]) has the knowledge to help them and that the physician will gather as much information as possible to offer effective treatment. Trust is important for both the patient and the physician. Patients who trust their physician are more satisfied. Physicians are in a unique position to provide social support to patients, and the long-term nature of many patient-physician relationships allows time for trust to develop in ways that can help patients physically and emotionally. While most of the studies emphasize the importance of the patient trust, there is little discussion in the literature on physician's trust for their patients. Patients who are nonadherent and those who simply cannot change problematic health behaviors threaten to erode trust on the part of their physicians. Therefore, it seems that part of the work of a physician involves some acceptance and understanding of the inherent difficulties involved with impacting patient change. It seems to me that a balance is required between the physician's sense of responsibility and the detachment needed to avoid feeling overwhelmed. In other words, there are limits to what physicians can provide. Although physicians cannot make patients magically change their unhealthy behaviors, the relationship between doctors and patients remains extremely important and can have a powerful impact on many patients[17].

The departure from the paternalist system, in which the physician was the subject making the decisions themselves, made the patient ultimately decide about the choice of therapy (from the one proposed by the doctor). This forces considering the attitude of trust between the physician and the patient as a bilateral relationship. As follows from the research carried out by Crooks *et al*.[18], the doctor's trust for the patient is also extremely important. The doctor should trust that, based on the information provided, the patient will make the right decisions about the choice of place and method of therapy. In general, therefore, it should be pointed out that the purpose of transmitting biological information and samples is to achieve a specific diagnostic or therapeutic goal consistent with the patient's good.

The character of trust being the basis for creating biobanks[19] and conducting research on human biological samples is completely different. In this regard, the

[15] S.D. Pearson, *Patients' trust in physicians: Many theories, few measures, and little data*, "Journal of General Internal Medicine" 2000, No. 7, pp. 509–513.

[16] S. Holland, D. Stocks, *Trust and its role in the medical encounter*, "Health Care Analysis" 2015, No. 3, p. 262.

[17] T. McClintock Greenberg, *The psychological impact of acute and chronic illness: A practical guide for primary care physicians*, San Francisco 2007, pp. 134–135.

[18] V.A. Crooks *et al*., *You don't want to lose that trust that you've built with this patient…: (Dis)trust, medical tourism, and the Canadian family physicianpatient relationship*, "BMC Family Practice" 2015, No. 16.

[19] R.T. Lawlor, A. Scarpa, *Models of collaboration and experience between bioindustry and academic biobanks*, (in:) E. Salvaterra, J. Corfield (eds.), *Advances in biobanking practice through public and private collaborations*, Bentham e-Book 2017, p. 18.

donor's interest gives way to the higher good that is the development of science and the health of future generations. Sometimes it is called public trust[20]. It is indicated that this is the reason of a gross expectation of patients' altruism[21]. Of course, this does not limit the possibility that the additional motivation (often the most important) of the donor participating in the study is the recognition that the results of the physician-scientist's work will contribute to finding a new therapy for the disease suffered by the donor. However, the donor does not receive any assurances that the research conducted on his biological sample will contribute to improving his health. Lack of confidence, therefore, makes it impossible to conduct any research on human biological samples[22]. In Estonia, where there is great confidence in physicians conducting research in the national biobanks, the biobanks have biological samples from 51,515 people[23], whereas in the Kingdom of Tonga[24], due to a lack of trust in physicians promoting the creation of biobank, there is no biobank.

4. FROM THE PATIENT TO THE DONOR TO THE PARTICIPANT OF BIOMEDICAL RESEARCH

The basic question is whether the donor of biological samples for biomedical research is always a patient?

The word "patient" is derived from the Latin word *patiens* which is translated as 'suffering and ill'[25] and therefore devoid of health. It is indicated that since the middle of the last century, the definition of health itself has been subject to enlargement. In the Preamble of the Statute of the World Health Organization, it was pointed out that health is a state of complete good physical, mental, and social condition, not just the absence of disease or infirmity. In connection with such

[20] G.N. Samuel, B. Farsides, *Public trust and 'ethics review' as a commodity: The case of Genomic England Limited and UK's 100,000 genomes project*, "Medicine, Health Care and Philosophy" 30 October 2017, https://link.springer.com/article/10.1007/s11019-017-9810-1 (accessed 11.04.2023).

[21] B. Daley, E. Cranley, *'Biorights' rise: Donors demand control of their samples*, "Boston Globe" 10 October 2016, https://www.bostonglobe.com/metro/2016/10/09/the-rise-biorights-donors-are-demanding-control-and-sometimes-cash-exchange-for-genetic-samples/jCbaQ2E5t6c0Qs1kcITMRM/story.html (accessed 11.04.2023).

[22] K. Moodley, S. Singh, *"It's all about trust": Reflections of researchers on the complexity and controversy surrounding biobanking in South Africa*, "BMC Medical Ethics" 2016, No. 10, p. 57.

[23] https://www.geenivaramu.ee/en/about-us (accessed 11.04.2023).

[24] J. Pawlikowski, *Biobankowanie ludzkiego materiału biologicznego dla celów badań naukowych – aspekty organizacyjne, etyczne, prawne i społeczne*, Lublin 2013, p. 49.

[25] M. Gałązka, *Status pacjenta*, (in:) M. Safjan, L. Bosek (eds.), *Instytucje prawa medycznego*, Warszawa 2018, p. 531.

a broad definition of health in the acts of international law, Polish law began to detach the term "patient" from the term "health".

The only act of European law defining the term "patient" is Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. According to Art. 3h of the Directive "patient" means any natural person who seeks to receive or receives healthcare in a Member State. In accordance with Art. 3a healthcare means health services provided by health professionals to patients to assess, maintain or restore their state of health, including prescription, dispensation and provisions of medical products and medical devices. Therefore, it can be concluded that not every person on whose biological samples scientific research is conducted is a patient.

Such a person is protected by separate legal acts, such as: Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin (Adopted by the Committee of Ministers on 11 May 2016 at the 1256th meeting of the Ministers' Deputies); Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research; WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks; and OECD Guidelines on Human Biobanks and Genetic Research Databases. In none of these acts the term "patient" appears. The terms used are only: "person", "research participant", and "participant". Therefore, it should be concluded that in European regulations there is no automatic recognition that the person from whom the samples are taken for the research purpose will be a patient and, therefore, detailed regulations in this respect belong to the laws of the Member States.

In Polish law, the definition of "patient" still evokes much controversy. In Art. 3 sect. 2 point 4 of the Polish Patient Rights Act and the Patient Rights Ombudsman, the "patient" was defined as a person seeking health services or benefiting from health services provided by the entity providing health services or a person performing a medical profession. In accordance with Art. 2 point 10 of the Polish Act on Healthcare Activity, the health service is an action aimed at maintaining, saving, restoring health and other medical activities resulting from the treatment process or separate provisions regulating the principles of their performance.

This imprecise definition of the provisions of health in Polish law in the past had created some doubts whether conducting research on human biological samples is a healthcare service or not. Gałązka indicates that "Defining a provision of health as a medical activity goes beyond medical intervention, understood as an impact on the human body. Therefore, it also includes medical activities on parts of his body disconnected from human, so the person from whom the cells, tissues or organs that are the subject of such activities come from, also has the status of a patient"[26]. Thus, only naturally a question arises what actions performed on

[26] *Ibidem*, p. 541.

human cells are medical activities? Traditionally, however, in the doctrine of Polish law it is pointed out that the provision of health is an action on a human, not on the parts of the body separated from it[27].

This legal situation was additionally complicated by the amendment to the Act on the Professions of Doctor and Dentist[28], which entered into force on 1 January 2021. In this amendment, the definition of a "medical experiment" was extended to include research on human biological samples. However, not all research on human biological samples is experiment within the meaning of this Act. An experiment is the research conducted on samples that have been collected for the purpose of scientific research (Art. 21 para 4 Act on the Professions of Doctor and Dentist). It is not clear from the justification of the Act why the legislator decided to introduce such a restriction. However, it should be acknowledged, *a contrario*, that conducting scientific research on samples that have been collected for other purposes, e.g. for medical purposes and later used for scientific purposes, is not considered a medical experiment, and thus is not subject to the new regulation. Thus, two different legal regimes arise for conducting research on human biological samples, one as part of a medical experiment, the other only on the basis of the patient's subsequent consent to use for scientific purposes the samples obtained from him for other purposes.

In the first case (of an experiment), according to the Act, such a person is not a participant in the experiment (because only the person on whom the experiment is conducted is a participant), but a person whose effects relate to. Therefore, the basis for conducting such research is not only private-law consent, but also public law norms stipulating the conditions for its conduct. Some of these additional conditions are somehow external to the patient-doctor relationship. It can be indicated, for example, that the doctor will have to obtain the consent of the biotic committee to conduct the research and insure the participant of the experiment. In such a case, it seems the influence of the doctor on the research has been reduced. The arrangements between the doctor and the patient are overlapped with the requirements set out in the opinion of the bioethics committee and resulting from the insurance contract, which naturally limits the scope of the doctor's liability. The question arises, however, whether this participant is also a patient. It seems that due to the fact that samples are from the beginning collected and tested only for scientific purposes, it is doubtful whether such a person can e considered as a patient.

In the second case, i.e. when the sample was collected as part of a healthcare services, and the collected biological material is used for a scientific purpose, the person remains a patient.

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[27] M. Boratyńska, P. Konieczniak, (in:) L. Kubicki (ed.), *Prawo medyczne*, Wrocław 2003, p. 32.

[28] Ustawa o zmianie ustawy o zawodach lekarza i lekarza dentysty oraz niektórych innych ustaw z dnia 16 lipca 2020 r. ("Journal of Laws" 2020, item 1291).

Therefore, there is no doubt that the donor from whom biological samples were taken for scientific purposes as part of a medical procedure will be recognized as a patient in both Polish and European law, although the donor will not always be a patient. This will be possible if the conducted research on the sample does not take place in an institution providing health services, e.g. at a research institute, and they are not run by persons performing medical profession, i.e. doctors, nurses or laboratory diagnostics.

Undoubtedly, it will be when the biological samples were taken during the treatment process in which case it should be clearly stressed that the physician is still obliged to use the data and samples for medical purposes and only in addition can use them for scientific purposes. However, due to the special moment of collecting these data and samples which is a medical service, the physician will be obliged to treat them as any other medical data – protecting the patient's rights. In this respect, one should also analyze two first cases, in which the doctor who conducts treatment of the patient uses his data and samples for scientific purposes. The other is one in which the doctor passes data and samples to other researchers (from his hospital or transmits them to the biobank).

In the first case, it should be considered whether the use of samples and data for testing was covered by the consent of patients and of what legal nature this consent would be. Such consent is not a consent to a medical procedure, sometimes it will take the form of consent for the collection of biological samples and data for research purposes, but it will be more often the consent to use already collected data and samples for medical purposes for scientific purposes[29].

4.1. THE PATIENT'S RIGHTS IN SCIENTIFIC RESEARCH ON HUMAN BIOLOGICAL SAMPLES

Traditionally, the following patient's rights can be distinguished in relation to the performance of scientific research on human biological samples: right to informed consent and free choice, right to clear information, right to confidentiality, and right to access to medical record[30].

According to Daher, the right to informed consent thus understood results from the fact that "Patients should be empowered to participate in decision making, and the healthcare team should respect those decisions. Any unauthorized touching of a person is battery, even in the medical setting. The patient's consent

[29] M. Goniewicz, R. Patryn, K. Goniewicz, A. Włoszczak-Szubzda, *Legal concept of consent as a declaration of intent to use genetic material*, "Revista Romãnã de Bioeticã" 2014, No. 1, pp. 15–23.

[30] M. Daher, *Patient rights,* (in:) H. Have (ed.), *Encyclopaedia of global bioethics*, Springer 2016, p. 2167.

allows the physician to provide care"[31]. It is difficult to point out, therefore, that the narrowly understood right to informed consent related only to the therapeutic decision-making process will apply here. Undoubtedly, conscious consent is a certain process of building mutual trust between a doctor and a scientist, and a patient. In practice, biological samples can be used for scientific research after prior consent of the patient or without it – on the basis of the legal act.

In the world's bioethical discussion, there are two issues concerning the use of biological samples obtained as part of medical treatments for scientific purposes without proper consent of the patient. The first is the case of Moor's[32] second covering of HeLa cells[33]. In both cases, cancer cells were collected from patients during medical procedures and out-targeting specific cell lines. The first case ended with a court ruling in California in which it was considered that the patient has no right to participate in profits from the results of scientific research. However, the court considered that due to the fact that Moore did not agree to commercial use of material taken from him, there was a violation of the fiduciary duty involving the proper representation of the patient's rights by the doctor. The second case, although not terminated by a court ruling, is referred to in the bioethical literature as an example of breaking the patient's right and abuse by the doctor. It should be noted that both cases have happened in the USA. No similar cases are known in European countries.

From the examples given above, it is clear that one's consent to use a biological sample and data related to it for the purposes of scientific research is not a consent to a medical procedure in the understanding of the patient's rights protection.

4.1.1. INFORMED CONSENT IN SCIENTIFIC RESEARCH ON HUMAN BIOLOGICAL SAMPLES

There is no doubt that the dominant approach to protecting the rights of donors in Europe is protection based on donor's informed consent[34]. This concept is highlighted in the 2001 Report of the National Bioethics Advisory Commissions, according to which engaging in the consent process is one of the best ways researchers can demonstrate their concern and respect for the participants[35]. In accordance with point 12 of the Word Medical Association's (WMA) Declaration

[31] *Ibidem*, p. 2168.

[32] Moore v. Regents of the University of California (1990) 51 Cal. 3d 120 [271 Cal. Rptr. 146, 793 P.2d 479].

[33] A. Aford et al. *HeLa cells and unjust enrichment in the human body – The Lacks family*, "Annals of Health Law" 2012, No. 1, pp. 224.

[34] B.S. Dörr, *Collection of human tissue samples in biobanks: Challenges to human rights and human nature*, (in:) M. Albers, T. Hoffmann, J. Reinhardt (eds.), *Human rights and human nature*, Springer 2014, p. 186.

[35] J. Murphy, *Public perspective in informed consent for biobanking*, "American Journal of Public Health" 2009, No. 12, p. 2128.

of Taipei[36], consent is valid only if it was preceded by information about: 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 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 (para 14). This right to information has also become a central mechanism guaranteeing the protection of donors' rights in the OECD Recommendations, such as the 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 provide biological material or data for third parties for non-testing purposes, the right to withdraw consent, about commercial products that may arise as a result of research on human biological samples or data and the benefits that the participant can relate to.

It is still emphasized that the problem of consent for conducting scientific research may determine the future of science. Meanwhile, it seems that the long-lasting discussion in the international forum on defining informed consent for the use of human biological samples for scientific purposes revealed the need to create new protective mechanisms[37]. In contrast to the concept of informed consent, understood as a consent to specific research in an increasing number of countries, the concept of broad consent is adopted[38].

According to the GDPR, there is also acceptance that the use of not all biological samples may be based on the conscious consent of the donor. Pursuant to Art. 5 (1b) of the 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 specific protection of the rights of donors associated with personal data may only be insufficient if based on informed consent[39]. In the days of Big

[36] 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.

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

[38] M.A. Rothstein, B.M. Knoppers, H.L. Harell, *Comparative approaches to biobanks and privacy*, "Journal of Law, Medicine and Ethics" 2016, No. 2, pp. 3–6.

[39] O. Tzortzatou *et al*., (in:) S. Slokenberga, O. Tzortzatou, J. Reichel (eds.), *Biobanking across Europe Post-GDPR: A deliberately fragmented landscape in GDPR and biobanking law, gover-*

Data and the merging of new data registers, it is difficult to clearly indicate at what stage the 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.

4.1.2. THE PATIENT'S RIGHT TO INFORMATION IN RESEARCH ON HUMAN BIOLOGICAL SAMPLES

According to the traditional definition, the patient's right to information assumes that "Patients should receive adequate information about their illness, possible interventions, and the known benefits and risks of specific treatment options. They should have the ability to ascertain names, roles, and the qualifications of those who are treating them"[40]. From the point of view of conducting scientific research it should be pointed out that the right to information in this field has a wider scope and includes the need to inform the patient that his data and samples will be used for research purposes, but also the right to obtain information relevant to his or her research. life and health obtained as part of the conducted research.

Lack of proper information on people who are sampled biological samples and data on the scientific objective may lead not only to breaking the trust between the doctor and the donors, but also to many violations of personal rights or even lead to discrimination of specific social groups[41].

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 identified with information that is received by the person who should be protected (patient, consumer) so that one 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, in 2014, analyzes were carried out from 22 European countries[42]. They clearly showed that action at European level was necessary as regards the necessity of introducing an obligation to provide information of importance to the patient in relation to his state of health.

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nance and technology series, Springer 2021, pp. 397–419; M. Kirwan *et al*., *What GDPR and the Health Research Regulations (HRRs) mean for Ireland: "Explicit consent" – a legal analysis*, "Irish Journal of Medical Science" 2021, No. 2, pp. 515–521.

[40] M. Daher, *op. cit*., p. 2168.

[41] Havasupai Tribe v. Arizona Board of Regents 1989.

[42] 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.

The postulate 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 ("a finding concerning an individual research participant that has potential health or reproductive importance and is discovered in the course of conducting research, but is beyond the aim of the study"[43]) is definitely more difficult for physician-scientist due to legal[44], economic, and organizational constraints[45]. Obtaining access to the results of these findings is still an important postulate of donors and patients[46].

The question arises whether in the absence of express consent the transfer of such information will not be a violation of the right to autonomy, of which the right to not know 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". 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 non-informed non-disclosure also follows directly from the Oviedo Convention. According to the wording of Art. 10, para 2, everyone has the right to read all the information collected about their 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 CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin No. 10, the patient's right to knowledge and ignorance should be recognized and professional mechanisms should be intro-

[43] S.M Wolf *et al*., *Managing incidental findings and research result in genomics research involving biobanks and archived data sets*, "Genetics in Medicine" 2012, No. 4, pp. 361–384.

[44] J. Bovenberg, T. Meulenkamp, E. Smets, S. Gevers, *Biobank research: Reporting results to individual participant*, "European Journal of Health Law" 2009*,* No. 16, p. 234.

[45] R.T. Lawlor, A. Scarpa, *op. cit*., p. 20.

[46] E.M. Bunnik, *Ethical framework for detection, management and communication of incidental findings in imaging studies, building on an interview study of researchers: Practices and perspectives*, "BMC Medical Ethics" 2017, No. 18, p. 9.

duced 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. Also, the Additional Protocol to the Bioethical Convention on genetic testing for health purposes[47] recognizes the right of every person to obtain information resulting from the 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. 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 physician also be responsible for the lack of information provided, which he would not obtain himself from the researcher? Fourthly, the question arises to whom this information should be transmitted, whether directly to the donor or to his doctor? Undoubtedly, the introduction of such an obligation will involve the need to include its costs in research projects[48].

Such a right is postulated both in the Declaration of Taipei and in 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 are also necessary. According to Art. 26 of the Additional Protocol to the Bioethical Convention on Genetic Testing for Health Purposes, participants should be given 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.

4.2. DONOR IS NOT ONLY THE PATIENT

The modern postulated model of cooperation between a physician and a donor patient also assumes increasing cooperation of these entities at the stage of conducting research[49]. The donor became a participant and even a research partner[50]. Some biobanks were established by patients[51]. This is particularly evident in the

[47] 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.

[48] A. Hawkins Virani, H. Langstaff, *Ethical considerations in biobanks: How a public health ethics perspective sheds new light on old controversies*, "Journal of Genetic Counselling" 2015, No. 24, p. 430.

[49] V.G. Koc, *A private rights of actions for informed consent in research*, "Seton Hall Law Review" 2015, No. 1, p. 1973.

[50] M. Boeckhout, R. Reuzel, G. Zeielhuis, in collaboration with E. Vermeulen, M.K. Schmid, A. Cecil, J.W. Janssens, *The donor as partner: How to involve patients and the public in the governance of biobank and registries*. A guideline prepared by BBMRI-NL 2014.

[51] D. Mitchell *et al*., *Biobanking from the patient perspective*, "Research Involvement and Engagement" 2015, No. 1, p. 8.

case of cooperation with physicians-researchers of organizations associating patients[52] with rare diseases[53] and large biobanks such as, for example, the UK Biobank[54] or the Genom Biobank in Estonia. In both cases, the donor patients, on the one hand, continue to provide new information and data about themselves, as well as periodically order new biological samples. On the other hand, they are informed about research carried out on their biological samples and sometimes even about the results of these tests that have a diagnostic significance for them. In modern biobanks donors and patients are very important part in making research policy[55].

The result of such a change in the subjectivity of donor patients in the absence of binding legal regulations is the recognition that in addition to the patient's rights, they also have the rights arising from the agreement concluded with the biobank, hospital or doctor. In practice, the content of this agreement will be confirmed in the patient's consent for the transfer of samples and data for research purposes. According to Giancarlo Pruneri and Giuseppina Bonizzi "(…) participation in research is completely transformed. Unlike previous models that attempted to impose on participants a robust duty to take part in research, a pact-based relationship instead provides participants with a strong incentive to do so, as they are motivated by an act of solidarity where participants, trust and belief that science in an ethical enterprise play mutual supportive roles"[56].

5. LEGAL RESPONSIBILITY OF PHYSICIAN SCIENTIST

Responsibility of the doctor-scientist towards the patient-supplier of human biological samples and data related to them will depend on detailed regulations contained in national legislation. Undoubtedly, however, under the law of the European Union and international declarations, certain general rules should be

[52] M. Wilcox *et al*., *The importance of quality patient advocacy to biobanks: A lay perspective from Independent Cancer Patients Voice (ICPV) based in the United Kingdom*, (in:) F. Karimi-Busheri (ed.), *Biobanking in the 21st century*, Springer 2015, pp. 171–183.

[53] Ch. Baldo *et al*., *The alliance between genetic biobanks and patient organisations: The experience of the telethon network of genetic biobanks*, "Journal of Rare Diseases" 2016, No. 11, p. 142.

[54] R.T. Lawlor, A. Scarpa, *op. cit*., p. 32.

[55] M. Verlinder, H. Nys, I. Huys, *Right and obligations of different stakeholders involved in access and use of samples and data in biomedical research*, (in:) E. Salvaterra, J. Corfield (eds.), *Advances* in *biobanking practice through public and private collaborations*, Bentham e-Book 2017, p. 92.

[56] G. Pruneri, G. Bonizzi, *Quality criteria in oncology: Lessons learned from B4MED Biobank*, (in:) E. Salvaterra, J. Corfield (eds.), *Advances in biobanking practice through public and private collaborations*, Bentham e-Book 2017, p. 70.

laid down regarding this responsibility based on the fundamental human rights[57]. For the purposes of this article, this responsibility can be divided into:

1. responsibility for improper processing of patient data,
2. responsibility for conducting research on a human biological sample without the consent of the patient,
3. responsibility for the operation of the subject to which the physician has provided/shared data or samples,
4. counter-agreement responsibility for non-performance or improper performance of the contract between the patient and the doctor,
5. tort liability for damage to persons related to conducting tests on human biological samples,
6. professional responsibility of the doctor.

The first kind of responsibility will be involved when the doctor processes the patient's data without a legal sub-platform, improperly secured it, prevented the patient from implementing the rights resulting from GDPR, processed data collected for health purposes for scientific purposes without the patient's new consent (the GDPR of course sets the principle according to which the treatment data for scientific purposes is always in line with the original goals, but at the same time it implies that if it is possible, the processor should obtain new consent from the person whose data is processed). The doctor will not be responsible in this respect if the data is anonymized (then they will not be subject to GDPR regulation) or if he will process the data of the deceased patient. However, in the case of data processing of a deceased patient, in many national jurisdictions the doctor was obliged to maintain medical confidentiality and hence not to disclose these data to other entities without the consent of the patient or his family members even after his death. In this case, it should be acknowledged that the doctor will have the right to conduct scientific research by himself, but he will not have the right to disclose data covered by medical confidentiality to other scientists. Certain doubts may arise as regards the possibility of the donor invoking the right to privacy. Traditionally, the right to privacy can be invoked if the data has been disclosed or made public in an unauthorized way.

The question open in this respect is whether violation of the right to privacy will therefore be any unauthorized transfer of patient's data to other scientists. In relation to the data, there may also be a breach of the contact obligations by the doctor, who, when obtaining permission to carry out the tests, assured the patient that the data will not be transferred to other entities, but later such transfer would occur or the non-compliant data would not be secured. In these cases, however, it should be emphasized that under condition of the physician's responsibility the injury of the patient could occur, which in practice would be difficult to demonstrate.

[57] P.K. Yu, *Biobanking, scientific productions and human rights*, "Legal Studies Research Paper Series" 2017, No. 17–73, p. 2.

In the second case, i.e. conducting scientific research without the patient's consent, one can undoubtedly point out the responsibility for the violation of patient's rights, such as the right to informed consent or the right to confidentiality of data. In this case, the patient will be able to demand reparation from the physician for dignity harms (caused by conduct that overrides patients autonomy)[58]. In addition, the patient may assume that as a result of the doctor's action undertaken without his consent, his personal good was violated. Recognizing the rather broad definition of health resulting from the Preamble to the Constitution of the World Health Organisation[59], one can also consider that the mere awareness that there has been a nauseous study without the consent of the donor may result in harm to the patient's psychological well-being. The doctor's action in this area may also be punished under professional or criminal law, depending on the regulation of domestic law.

When analysing the third case, it should be pointed out that the scope of the physician's responsibility for the subjects who provided the samples and the patient's data may vary. Undoubtedly, the doctor will be responsible for these entities and for his own actions when the transfer took place without the consent of the patient or without a legal basis. However, if the transfer will have a legal responsibility, the doctor will not perform or will be limited by the content of the contract.

The fourth case is still the subject of few doctrinal studies.

The physician's responsibility in this respect will be shaped on the basis of quasi-contractual liability and on this basis he will be responsible for improper performance of the contract and, therefore, for the use of samples not in accordance with the purpose or unauthorized transfer to other entities. In both cases, the liability will arise when the patient will suffer harm as a result of the doctor's actions.

This agreement is difficult to regard as a typical obligatory relation of medical law. Banaszczyk[60] rightly points out that the essence of such a relationship is the obligation of a person performing medical activity to take and conduct treatment and to pay the patient due remuneration. The transfer of samples and data to the doctor for scientific research is of an altruistic nature. Therefore, it is difficult to point to binding obligations on the part of the patient who, even after consenting to carry out such tests, may withdraw it at any time. On the other hand, the doctor has a number of obligations arising from the patient's rights and, in particular, the

[58] V.G. Koc, *op. cit*., p. 202.

[59] The Constitution was adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States and entered into force on 7 April 1948. Later amendments are incorporated in this text.

[60] Z. Banaszczyk, *Właściwość i elementy prywatnego stosunku prawa medycznego – założenia ogólne i metodologiczne*, (in:) M. Safjan, L. Bosek (eds.), *Instytucje prawa medycznego*, Warszawa 2018, p. 358.

need to protect the rights of the donor. With respect to this responsibility, one can point to additional obligations not resulting from the law. Sometimes doctors and biobanks in which they work will guarantee patients additional rights such as the right to information about research finding[61] or free laboratory tests.

Analysing the liability of a tort, it should be considered that it is connected with the same problem o contractual responsibility, i.e. the need to prove the suffered damage. It is difficult to indicate the possibility of damaging the property as well as damage caused to the human body. One can only rely on the fact that the culpable action of a doctor who, for example, publicized the patient's data in a scientific publication, caused the patent mental suffering or even a mental illness.

Finally, referring to the doctor's professional responsibility, it should be pointed out that he will be responsible for all violations of the patient's rights. It should be clearly stressed that he is obliged to provide all medical information known to him that is relevant to the health and life of the patient, including incidental findings[62]. There is no doubt that only the doctor who knows them (regardless of whether he was a patient's doctor or not) has an obligation to inform about incident findings and he is able to contact the patient (this possibility will not arise if the patient's data were subject to anonymization or due to procedural reasons re-contact with the patient is impossible, eg. when the doctor has no contact details[63]).

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[61] Without special agreement there is no right to information about the study. More about this issue B.M. Knoppers, *The right not to know*, "Journal of Law, Medicine and Ethics" 2014, No. 1, p. 8.

[62] V.G. Koc, *op. cit*., p. 176.

[63] More about this issue G. Helgesson, *Autonomy, the right not to know, and the right to know personal research results: What rights are there, and who should decide about exceptions?*, "Journal of Law, Medicine and Ethics" 2014, No. 1, pp. 29–37.

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