Article

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Discussions on the Status of the Ethics Committee and Biobanking Practices in the Nordic Countries

Vladimir I. Przhilenskiy

Kutafin Moscow State Law University (MSAL), Moscow, Russian Federation

Abstract: The article analyzes the institutional status of the ethics committee as a social regulator. The object of the study is the practice of legal and administrative regulation in the field of application of genetic technologies in the Nordic countries. To this end, a comparative analysis of national legislation and practices regulating the activities of biobanks in these countries is carried out. Particular attention is given to the legal status of the ethics committee, the possibility of the ethics committee performing a regulatory function, as well as its relation to the legal system, is being investigated. Various positions concerning the legitimization of the decisions of the ethics committee in modern literature are considered. The heterogeneity of this institution is determined, which makes it possible to consider it both as legal, administrative and metaethical social regulators.

Keywords: ethics committee; biobank; genetic technologies; Nordic countries; genomic research; social regulator; law; bioethics

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Contents

I. Introduction

Modern society has been considered informational for more than half a century. Although collection of information, its storage and processing have been among the vital spheres of human activity since ancient times, it is in recent decades that their importance has grown significantly. Genomic research, the use of genetic technologies and the development of precision medicine resulted in the birth of a special information sphere — biobanking. This area includes collection, storage and use of different types of biomaterials, including human biomaterials. In connection with the above, issues of legal and ethical regulation of the collection and storage of biomaterial and other genetic data are of particular importance. The legal regulation of genetic research is steadily improving, but still does not keep up with the development of genetic research itself, especially in the field of the development and application of technologies based on their achievements.

A distinctive feature of this area of law at present is its higher dependence on ethics, which led to the creation of a special institution — the ethics committee, combining the possibilities of ethical and legal expertise, but at the same time giving rise to numerous problems of

both organizational and substantive nature. Some of these problems are reflected in discussions about the relationship between ethics and law, the epistemological status of bioethics, etc. For example, the domestic literature expresses the thesis that the organization and conduct of ethical examinations, unlike legal ones, is much better regulated and can be carried out within the framework of the current regulatory framework. Meanwhile, the need for legal expertise in the field of genomic research and genetic technologies is no less, if not greater, which is confirmed by the lack of legal support for many important decisions of the authorities and actions of research teams. The opinions of scientists, lawmakers and the general public often differ in the assessment of the powers of ethical committees, and in the possibility of their attribution to the sphere of law or morality. In this regard, it seems appropriate to study the experience of the work of ethical committees in the Nordic countries, as well as the practice of legal regulation in these States. But first it is necessary to analyze the theoretical concepts of the legal status of the ethics committee that exist in modern science.

II. Decision of the Ethics Committee: Together with the Law, instead of the Law or a Special Kind of Law

The history of bioethics teaches us that its emergence was associated with a qualitative change in the situation in medicine appeared due to the emergence of new technical capabilities and devices, technologies for the diagnosis and treatment of patients. Bioethics received a new powerful impetus due to the development of genetic technologies that have found application not only in medical institutions, but also in research laboratories, where they searched for answers that not only doctors, but also biologists, breeders, anthropologists, historians, criminologists posed. In a completely different way, the problem of what can and cannot be done in the clinic and laboratory, what steps can and cannot be taken in the process of treatment, study, production, collection and processing of information was posed. Consumer genomics has become a separate high-tech, investment attractive and highly profitable business sector. With the development of the field of genomic research and the use of genetic technologies, it became

increasingly obvious that conventional legislation and traditional ethics systems were not suitable for its regulation. Moreover, their inability to effectively regulate this area was connected not only with the content of regulatory legal acts or moral theory — the very mechanism of their creation and implementation made the performance of the assigned function impossible.

The rule makers were unable to foresee all the contradictions between research interest and ethical principles that arise in the process of development of this rapidly growing and becoming more complex branch of knowledge. Moral theory with religious or humanistic roots was even less suitable for this. Divine revelation and creative experience turned out to be not so universal, first, in matters of their interpretation, the mechanisms of which could not but be conditioned by numerous cultural-historical, ethno-confessional and even political contexts. Researchers, doctors and technologists faced the question of a fundamentally different method of obtaining an answer to the question whether it is possible or impossible to do such actions, having a certain degree of knowledge about their possible results. It was even necessary to redefine the role of philosophy in bioethics, arguments in favor of a new functional were in demand alongside the increasing status of philosophical knowledge. Jennifer Blumenthal-Barby, Sean Aas et al. write "We do not mean to imply that philosophy is the only discipline that has an important role to play in the field of bioethics. Our point is simply that philosophy still has a very meaningful and important role to play in bioethics — not just the branch of philosophy that is ethics, but many other branches of philosophy as well. If anything, philosophy has a central and expanding role to play in bioethics. The field of bioethics could benefit from acknowledgement of this in light of recent skepticism" (Blumenthal-Barby et al., 2022, p. 10).

One of the topics hotly discussed today in connection with the correlation of philosophy and bioethics is the complexity of organizing bioethical, biomedical and legal expertise in the field of genomic research and the use of genetic technologies. Undoubtedly, the participants of the discussion regularly return to the problem of the legal, bioethical and epistemic status of ethical committees. Still, other difficulties may arise in addition to the philosophical interpretations of the essence and

specifics of the ethics committee itself: its competence remains rather unclear. Andrew Moore and Andrew Donnelly draw attention to the fact that ethics committees are forced to solve two different tasks. The first task of an ethics committee is to ensure that the research project is evaluated in terms of the current legislation (code-consistency review of proposals for consistency with the applicable code), while the second is to verify the feasibility of ethical standards and requirements (ethics-consistency review of proposals for ethical acceptability). "'Code-consistency review' and 'Ethics-consistency review' describe each potential job in turn. 'Relations between the two sorts of review' argues that the two are distinct in principle and practice. 'Combining code-consistency and ethics-consistency review' identifies different ways in which authorities could establish combinations of code-consistency and ethics-consistency review and argues that each is problematical" (Moore and Donnelly, 2018, p. 481).

It is possible to agree with Moore and Donnelly that the performance of two such different tasks by the same authority challenges the results of its expertise. The point here is not only a conflict of interests; the tasks themselves are heterogeneous, because they are designed to solve problems caused by different reasons. The need for a special assessment of the project for compliance with the laws is caused by the quality of the laws themselves as they can create legal uncertainty. No matter how perfect the law is as Moore and Donnelly rightly state, it is impossible to provide for all cases requiring legal expertise, because at the design stage of scientific research there is a limited idea of what awaits the researcher ahead. If we are talking about the compliance of the project with bioethical norms and principles, then the situation here is qualitatively different. It is not the opacity of the wording of the law that matters here, but the predictability of the consequences of the implementation of the plan developed by the researchers.

Thus, if situations of legal uncertainty are solved with the help of the law itself, then situations of divergence of law and ethics can be solved either by destroying the law, or by rejecting certain principles or, in extreme cases, mitigating them. Moore and Donnelly state that "Ethics-consistency thinking will tend to run together the matter of which factors are apt to be considered at review with the matter of which

issues are 'ethical issues.' Focus will tend to accrue to such questions as: Is the lawfulness of a proposed activity an ethical issue? Is the scientific quality of a proposal an ethical issue? Principled answers to such questions are difficult to give, unless one appeals to some controversial and reasonably rejectable conception of ethics while also rejecting other such conceptions" (Moore and Donnelly, 2018, p. 486). At the same time, the authors note that the difference in the understanding of ethics itself by Aristotle and Mill, on the one hand, and Kant, on the other, retains its significance to this day, which creates additional difficulties in determining the regulatory status of ethics-consistency review of proposals for ethical acceptability. It is important to to recall that the tradition coming from Aristotle does not separate ethics from law, and Kant's concept of moral philosophy is based on the differentiation of these areas (and these regulators). Considering the above, Moore and Donnelly propose to rename the "ethics committees" into "supervisory boards," depriving them of some of their powers today.

Moore and Donnelly propose that the definition of the functions of the ethics committee, its status and powers depends on some or other ethical theory and that legislators have to choose between different ways of philosophical reasoning and justification. Søren Holm strongly disagrees with this argument. "Research ethics committees are not philosophy seminars, and their job is not to try to shape research projects in a way so that they are ethically optimal. Their job is to make sure that the research is ethically acceptable. This means that they should only deviate from the code if the code leads to a result that is ethically unacceptable. Because there is space between what is ethically acceptable and what is ethically optimal or ideal, it is not the case that a research ethics committee '…must be empowered at review to revise those standards when this would make for an ethical improvement'" (Holm, 2018, p. 488).

Søren Holm, criticizing the article by Moore and Donnelly, notes that ethical committees cannot and should not reproduce the activities of philosophers whose thought was aimed at finding the right solution, chosen from a certain number of alternatives. The members of the ethics committee only determine what in the research project under consideration falls under the scope of legislative prohibitions, without

touching upon the topic of moral prescriptions or ethical preferences. Matti Häyry defends the same point of view. "Their primary professional task is to clarify distinctions, explicate arguments, and analyze judgments by examining their background assumptions — their presuppositions. It is important, I believe, to realize that the concrete normative judgments ethicists make will eventually rest on a prior subjective or intersubjective choice of presuppositions, not on any bedrock of perennial philosophical wisdom" (Häyry, 2015).

The position expressed by European researchers Helga Nowotny and Giuseppe Testa consists in the fact that bioethics cannot, in the strict sense, be attributed either to the sphere of morality or to the field of law. According to these authors, bioethics from the very beginning acted as a new type of social regulator, located together with the law, but not dissolving into it. Nowotny and Testa call bioethics a humanitarian regulatory technology, which occupies a place in a complex regulatory system that includes, in addition to bioethics, legislation and administrative management, or rather the type of it that they call governance. They qualify this new humanitarian technology as a kind of social technology or technology of humanitarian standardization. "The spectrum of norms that are involved in the greatest possible participation of the actors is accordingly diverse — state and international law, conventions and habits, soft law and good governance. Governments, nongovernmental organizations (NGOs), and industries have differing norms but have joined together in network governance. It is tacitly presumed that the exercise of governance already guarantees the democratic political quality of the outcome, since the securing of democratic legitimacy lies in the diversity of the participating actors. Measured against the standards of democratic representation, however, the democratic quality of governance proves to be problematical — all the more so because its arenas are often decoupled from the institutions of representative democracy" (Nowotny and Testa, 2010, p. 78).

Nowotny and Testa discuss the birth of a new type of sociality that mainly differs from the former one not only that there is the emergence of new social regulators and the renewal of old ones. Modernization concerns all elements of society, not just the legal system: management technologies and social institutions must be radically transformed,

socially significant goals and values must acquire a new meaning. According to Nowotny and Testa "the aim is to create standards that permit a change — a reshaping — of forms of life. A deeper convergence of the molecular age is thereby revealed. Human technologies that have reached a certain degree of societal maturity are converging with a biology that is open to societal goalsetting, to taking legal and ethical limitations into account from the beginning, and to including them in its design. Common to both is that they are complex systems that should be disassembled" (Nowotny and Testa, 2010, p. 83).

A common idea was the mention of the fact that traditional forms of regulation of genetic research are increasingly failing. Traditional algorithms for resolving ethical contradictions that arise in research laboratories and medical clinics are extremely inefficient. This applies equally to both the level of international law and national regulatory systems.

As already mentioned, the classical understanding of morality and law was under attack due to the rapidly developing branch of knowledge and activity — the field of genomic research and the use of genetic technologies. Reducing all possible actions to a relatively small number of principles and a bureaucratic understanding of their application does not achieve its goals where questions arise about informed consent and cloning, genome editing and precision medicine. As noted by Silvia Camporesi and Giulia Cavaliere "knowledge of and training in moral philosophy are not sufficient for successful work in bioethics. As part of their public role, bioethicists are often asked to comment on recent developments or controversies and make judgments about the most appropriate course of action. As such, it is critical that they understand the relevant features of a particular issue or controversy and the historical, social and political context in which it is situated. In order to do so, bioethicists need to develop a relational or interactional type of expertise" (Camporesi and Cavaliere, 2021). The specificity of bioethics as a social regulator is that people with a different set of competencies participate in the development and decision-making, and the mechanism of forming a bioethical committee itself turns out to be a challenge to established foundations. The mechanism of formation of the ethics committee acts as an alternative to the mechanisms of

formation of the legislative assembly, which forms the law as a social regulator. On the other hand, the appearance of ethical norms within the framework of religious or philosophical doctrines about good and evil, existing and due, etc. is less formalized, but also sanctified by tradition. Tradition and authority confirm the confirmation of legitimacy in both the first and second cases, while the ethical committee uniting politicians and journalists, public activists and scientists is still formed quite arbitrarily. That is why the question arises whether the members of the ethics committee are able to act as alternative experts in ethics and law, medicine and biology, pushing aside specialists whose involvement was previously confirmed by relevant academic degrees and scientific publications.

III. Key Features of Biobanking in the Nordic Countries

The Nordic countries, after joining the European Union, consistently bring their legislation into line with the norms and principles developed and adopted by the supranational structures of the EU and European bureaucrats. The sphere of functioning of biobanks has not become an exception, discrepancies in the rules of functioning of which are often considered as one of the most serious obstacles to genomic research and the use of genetic technologies. In the rapid development of this field of science and practice related to the field of high technology, effective cooperation between different countries in the field of research is especially important. One of the main difficulties for legislators and law enforcement officers is the practice of using personal data that primarily includes medical and genetic information related to individuals, including patients receiving treatment and other voluntary participants in scientific research.

Of great importance for the unification of the national legal systems of the Nordic countries was the adoption of the EU General Data Protection Regulation (GDPR)[1] in 2016 and its application since May 2018. "Although the GDPR is not a research regulatory tool, in an attempt to regulate the processing of personal data, it creates a rather

[1] General Data Protection Regulation (GDPR). Available at: https://gdpr-info.eu/ [Accessed 07.09.2023].

complex 'research regime,' also known as the 'scientific research regime' or 'research exemption,' through which it determines how scientific research is regulated in relation to personal data" (Slokenberga, Tzortzatou, and Reichel, 2021, p. 1). The advantages of GDPR include the fact that the law contains strict requirements for the processing of medical and genetic data. The rights of the data subject and the obligations required of biobanks and research teams in relation to them are clearly legislated. The possibilities of deviation from these rules are indicated when it is necessary to achieve the goals of scientific research. The GDPR text sets guidelines for the development of national special laws and biobanks or for the adaptation of other regulations that perform their functions.

IV. The First Biobank Law: The Interaction of Genomics and Law in Sweden

In its development of biobanking, Sweden, like other Nordic countries, does not lag behind such world leaders as the USA, Great Britain, as well as other EU countries. In total, Swedish biobanks have accumulated more than 150 million preserved samples taken from humans or fetuses. Research institutes and centers, as well as medical institutions study them. The number of biobanks is also growing, which has already exceeded three hundred, which is quite a lot for a country with a population of ten million. Back in 2002, Sweden adopted a special law on biobanks.[2] Its disadvantages include the fact that the text of the law, like the texts of many other similar acts of the beginning of the 2000s, establishes only general requirements for the creation and operation of biobanks. The practice of developing genetic technologies and conducting scientific research inextricably linked with their application has shown the limited nature of the norms proposed by legislators, calling into question the effectiveness of such regulation. The recommendations of the Council of Ministers of the Council of Europe on

[2] The Swedish Biobanks in Medical Care Act (SFS 2002:297). Available at: https://www.global-regulation.com/translation/sweden/2989107/law-%25282002%253a297%2529-om-biobanks-in-health-care%252c-etc.html [Accessed 07.09.2023].

the research of biological materials of human origin in the 2016 edition mark an important step towards the unification of national legislation, and also marks a movement towards detailing what until recently was considered unimportant and not subject to legal regulation.[3]

Magnus Stenbeck, Sonja Eaker Fält and Jane Reichel commenting on the content of the Swedish biobank law in relation to personal data note the minimalist approach demonstrated in Art. 89 to limit the possibility of using biobank materials in future research. They explain this by the fact that Swedish legislation pays considerable attention to the right to public access to official information. The problem is that the confidentiality rules for different categories of information differ, which prevents the effective use of different state registries in research: linking personal information obtained from biobanks with personal information from other databases (national statistical population registers, national clinical registers, etc.) turns out to be difficult and sometimes impossible (Stenbeck, Eaker Fält, and Reichel, 2021, p. 379). Thus, Stenbeck, Eaker Fält and Reichel conclude that "the Swedish regulatory framework allowing for the use of health data for scientific purposes, on the one hand, is quite liberal, giving researchers wide access to registers, but, on the other hand, it can be a source of legal uncertainty (ambiguous). No specific legal basis for the processing of personal data in research has been introduced by law, but the Government has indicated that this is not necessary, given the already existing legal context in which public interests are a priority" (Stenbeck, Eaker Fält and Reichel, 2021, p. 394).

Thinking of the development of legal regulation of genomic research and the use of genetic technologies, the legislators of Northern Europe strive to take into account the best world practices. This has resulted in the adoption of a number of regulatory legal acts on biobanking as a type of bioresource collections. These include the Swedish Biobank Act effective as of 1 July 2023. The authors of the bill claim that the new legislation will be much better than the previous one (Law on Biobanks of 2003) in terms of regulation of the conduct of scientific

[3] CM/Rec(2016)6). Available at: https://search.coe.int/cm/Pages/result_details.aspx?ObjectID=090000168064e8f [Accessed 14.01.2023].

research and the work of medical institutions. The rulemakers managed to take into account their own and foreign experience of the functioning of the science and healthcare system to eliminate excessive administration, while maintaining the necessary level of protection of donors' rights. Lena Hallengren, Minister of Social Affairs, states that "Biobanks are important for research and healthcare, including diseases such as cancer. The current Law[4] on biobanks is almost twenty years old, and it needs to be modified."[5]

According to the information in the media, the new law will also regulate how identifiable biological samples will be collected, stored and used without the threat of violating the rights of donors and privacy. It is assumed that the new Biobank Act will take precedence over most other national laws and legislative acts of the European Union. "Consent to the collection and preservation of samples for the care or treatment of a donor is not required if the patient has consented to care or treatment in accordance with the Law on Patients or the Law on Dental Care and has received certain information in accordance with the Law on Biobanks. The Ethical Review Body or the Ethical Review Appeals Board have to basically request information and consent for the processing of samples for research. The rules for providing samples outside the biobank are being clarified and a new possibility of sending samples for a certain measure is being introduced. The general ban on storing samples abroad has been lifted.

V. Development of Biobanking in Finland

The Finnish Biobank Act was adopted in 2012 and its text is much more specific in terms of content than the Swedish one. A decade later, many problems were seen differently, and the ways to solve them were suggested by practice. In the preamble, the main purpose of the law is "to support research in which human biological samples are used, to promote openness in the use of these samples and to ensure the

[4] Here Lena Hallengren speaks about the Law on Biobanks of 2003.

[5] New Biobank Law in Sweden will Facilitate Research and Healthcare. Available at: https://www.biobanking.com/new-biobank-law-in-sweden-will-facilitate-research-and-healthcare/ [Accessed 14.01.2023].

protection of privacy and self-determination in the processing of these samples."[6]

The difference between the Finnish Biobank Act and the Swedish one is the definition of the place and role of the National Committee on Medical Research Ethics, which allows us to talk about legislative support for institutional and infrastructural aspects of regulating genetic research in this area. The Swedish law mentions only the National Board of Health and Welfare, while the Finnish legislation prescribes sufficiently the mechanisms of interaction between ethical and legal aspects of regulation, including the functionality of ethical committees. The Finnish Biobanks Act stipulates that the National "ethics committee must determine whether the activities of a biobank comply with the conditions regarding the protection of privacy and the right to self-determination set out in this law and in other laws and provide an informed opinion on the ethics of the activity."[7] And they must do this no later than in two months' period.

A significant advantage of the law under consideration is the regulation of the duties of the biobank's custodian. According to the Act, the custodian of a biobank must attend to: "performing quality control for the samples being stored; maintaining, linking and protecting registers and databases; ensuring the protection of privacy when processing samples and information related to them; safeguarding the code key and supervising its use; realising the the right of access to information; other duties of custodians, provided in this act."[8]

Finnish legislators have significantly modernized the national system of legal regulation of genomic research and the use of genetic technologies, especially in the field of biomedicine. They are drafting amendments to the current Biobank Act, taking into account the requirements of the GDPR. In January 2019, a new Data Protection

[6] Biobank Act. Ministry of Social Affairs and Health, Finland. Available at: https://finlex.fi/en/laki/kaannokset/2012/en20120688.pdf [Accessed 07.08.2022].

[7] Biobank Act. Ministry of Social Affairs and Health, Finland. Available at: https://finlex.fi/en/laki/kaannokset/2012/en20120688.pdf [Accessed 07.08.2022].

[8] Section 8. Duties of the custodian of a biobank. Biobank Act. Ministry of Social Affairs and Health, Finland. Available at: https://finlex.fi/en/laki/kaannokset/2012/en20120688.pdf [Accessed 07.08.2022].

Act came into force; its main difference from the previous one is its compliance with the spirit and wording of the GDPR. The emerging system is completed by the Act on the Secondary Use of Health and Social Data, which gradually comes into force from May 2019 (Southerington, 2021, p. 244). Art. 89 of the GDPR made it possible for Finnish legislators to allow derogation from certain rights of the owner of personal data for the purpose of conducting scientific research, compensating for this with strict guarantees that apply, among other things, to the entire data set, and not only to personal data.

VI. Unique Character of the Danish Model of Legal Support for Genetic Research

Denmark's experience in this area is completely different. The specifics of the Danish approach to the legal support of the creation and use of bioresource collections, primarily genomic databases and biobanks, is that regulation itself is not carried out through the development of a special law on biobanks. The Danes seek to explore the regulatory potential of the already existing general laws that ensure confidentiality, information protection and privacy. Here it is appropriate to refer to the opinion of a Danish expert Mette Hartlev who notes the sufficiency of the Danish Health Act[9] and the Danish Criminal Code[10] as to the legal maintenance of the functioning of bioresource collections, including biobanks (Hartlev, 2015). Other laws and administrative rules fully compensate the absence of a special law. According to Mette Hartlev an important role here plays the understanding of the general meaning of law and the guiding principles in general. Art. 72 of the Danish Constitution[11] that protects the inviolability of the home, the secrecy of letters and communications regulates privacy protection.

[9] Consolidating Act No. 2014 of 14 November 2014, Act on Health. The Health Act (No. 546 of 2005). The Health Care Act. Consolidating Act No. 1202 of 14 November 2014.

[10] Consolidating Act No. 871 of 4 July 2014, Criminal Code, Sections 152b-c and Section 264d. Consolidated Act 1068 of 6 November 2008, The Consolidate Penal Code (Consolidate Act No. 976 of 17 September 2019).

[11] Denmark's Constitution of 1953. Available at: https://adsdatabase.ohchr.org/IssueLibrary/DENMARK_Constitution.pdf [Accessed 07.09.2023].

Protection is provided through "three main legal regulatory procedures, including the general rights of patients (especially the right to self-determination and confidentiality), the regulation of research and data protection laws" (Hartlev, 2015, p. 745).

Experts of the Organization for Economic Cooperation and Development in Europe consider this "general information" approach of Denmark not only acceptable, but also advanced. The Danish Data Protection Act adopted in Denmark in 2000 is based on the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108)[12] and Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.[13] The general rules for the processing of personal data and the protection of access to them by third parties are recognized as very effective. It was the Organization for Economic Cooperation and Development that adopted the Recommendation on Health Data Governance[14] in 2016 (Russia participated in its development). Currently, they are developing some indicators to assess the implementation of the 12 principles set out in Recommendation by countries that adhere to them. At the same time, the Danish regulation experience is considered among good practices that law makers relied on, along with Icelandic models of agreements between ministries in Iceland on coordination and cooperation between bodies that process health data.

The Danish model of processing personal health data is regulated by special rules that aim at excluding the very possibility of revealing such information as sexual life, race or nationality, political views,

[12] Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No. 108). Council of Europe. Strasbourg, 28.01.1981. Available at: https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=108 [Accessed 07.09.2023].

[13] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on The protection of individuals with regard to the processing of personal data and on the free movement of such data. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31995L0046 [Accessed 07.09.2023].

[14] Recommendation of the Council on Health Data Governance. Available at: https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0433 [Accessed 07.09.2023].

religious or philosophical beliefs, and participation in trade unions. The text of the Danish Law also contains possible exceptions to the general rule: these are the needs of preventive medicine, medical diagnosis, provision of care or treatment, or management of the health care system. A special case is the permission for the processing of data by medical professionals, because they are bound by obligations clearly established in the legislation on professional secrecy.

As M. Hartlev notes "the Danish regulatory framework for research in the field of biobanks can be described as 'research-friendly.' Explicit consent of the research participant is required only in projects in which individuals are recruited directly as volunteers. In other situations, patients and persons who have previously participated in research are assumed ready to provide samples for the needs of the study. If this is not the case, the person must actively refuse to participate, but it is not possible in some situations. In this regard, the question arises whether the current disposition corresponds to Section 1 of the Law on the Review of Ethics of Research in the Field of Health. (5Act No. 1436 or 17 December 2019 on amendment of the Act on Research Ethics Review of Health Research Projects)" (Hartlev, 2021, pp. 225–226). M. Hartlev emphasizes that despite the need to respect human rights and protect privacy, it is necessary to turn to the concept of a solidarity approach, when "we as individuals are obliged to society, especially in the context of a welfare society like the Danish one." Thus, the Danish law on research ethics in the field of healthcare, declaring loyalty to the values of humanism and anthropocentrism, also contains a reference to the interests of society and science. According to M. Hartlev these very interests of society and science allow a deviation from strict compliance with the requirement of informed consent that in practice becomes the rule rather than an exception.

The Danish legislation regulating the creation and use of such bioresource collections as the medical biobank is in close relationship with the corresponding infrastructure. The Statens Serum Institute (SSI) was created under the auspices of the Danish Ministry of Health and specializing in the fight against infectious diseases and biological threats or the organizational and institutional support of this system. "SSI houses the Danish National Biobank, which stores more than

22 million biological samples, such as serum, plasma, leukocyte film, whole blood and DNA. The main goal of the Danish National Biobank is to provide scientists from Denmark and other countries with an overview and access to biological samples in both existing and future collections. Scientists have the opportunity to link information about biological samples in Danish biobanks with a large volume of data contained in Denmark's unique health registers."[15]

The Institute is creating new registers of the data registered and approved by the Danish Data Protection Agency. With the mandatory approval of the Ethics Committee, external researchers and SSI employees can process data from the SSI biobank that stores the samples of two-thirds of Danes in its repository. Thus, no prohibitions will stay in the way of a research project implementation and it will be possible to link the data from the SSI bioresource collections to the data from other collections. It is not difficult to see the special role of SSI in the overall system of governance and regulation of genomic research and the use of genetic technologies both in medicine and in other areas of social life.

In order to gain access to health data from the SSI bioresource collection, which create an opportunity for the identification of the subject, researchers must prove it necessary in his project. An application form is available on the SSI website and it requires specifying the goals and methods of the project, which make it possible to estimate the volume of necessary data sets requested by researchers. The institute receives about two thousand of applications annually. The procedure for the regions and municipalities submitting applications to obtain data on the health of individuals is separately specified. According to the license agreement signed by the parties, the Institute exchanges data with regions and municipalities through a special web portal, the data protection of which is considered sufficiently reliable. The Danish Data Protection Agency thoroughly investigates all cases of unauthorized access attempts to the web portal resources.

The most difficult issue for legal regulation is the reuse of data voluntarily provided by donors supported by the informed consent. As noted in the report of the Organization for Economic Cooperation and

[15] *See*, Statens Serum Institute (SSI). Available at: https://en.ssi.dk/ [Accessed 07.09.2023].

Development, "in Denmark, the volume of data related to biological materials (genetic data) is growing; the use of this data in projects involving linking with other health data is expanding. In this regard, the risk of re-identification of biological data is currently being discussed in Denmark. In particular, the issue of consent to the use of biological data is being discussed and whether such consent should be broad (i.e., allow the use of data for subsequent research without the requirement of re-obtaining consent)."[16]

Thus, the general structure of the Danish health data governance system emerges, that is, the system of legal and administrative regulation of bioresource collections. It includes the Statens Serum Institute (SSI) research institute, the Danish Data Protection Agency, and the Danish National Committee on Biomedical Research Ethics. The third element, the ethics committee, plays approximately the same role in this triad as in systems that consider biobanks as subjects of special regulation.

VII. Icelandic and Norwegian Systems of Legal Regulation on the Legal Map of Northern Europe: The Search for the Golden Mean

Another Nordic country, Iceland, finds itself between Sweden and Finland in a comparative analysis of biobank legislation. On the one hand, the Icelandic national law was adopted two years earlier than the Swedish one — in 2000. However, the amendments and supplements made thereto have significantly changed the effect of all its main articles. Such changes were made three times: in 2008, 2009 and 2014.

As in other similar laws, the purpose is to authorize the collection, storage, processing and use of human biological samples. The experience of conducting genetic research, as well as the development and application of genomic technologies, forced the rule makers, in addition to the samples themselves, to refer medical data collected for scientific research to the objects of regulation.

[16] Big data for sound health. Denmark Experience. Available at: https://oecd-russia.org/analytics/bolshie-dannye-dlya-krepkogo-zdorovya-opyt-danii.html [Accessed 08.08.2022]. (In Russ.).

The law prohibits the use of stored data, which could result in "discrimination of a person on the basis of information obtained from his/her biological sample [or health data]."[17] Storage of gametes and embryos (artificial insemination and use of human gametes and embryos for stem cell research), removal of organs or remains are separately regulated; compliance is established with another legislative act — the Cultural Heritage Act.[18]

Norway occupies a special place on the legal map of genetic research regulation in Northern Europe. The development of this sphere of regulation in fact began alongside the drafting the Act on medical and health research (The Health Research Act) that was adopted on 20 June 2008. This law came into force on 1 July 2009, the same day when they issued the Regulations on the organisation of medical and health research, which answers the most provocative questions on the matter.[19] The bill, which was presented in Odelsting as Proposition No. 74 (2006–2007), was based on the Norwegian Official Report NOU 2005:1.[20]

The main task set by the Norwegian rulemakers is the revision and simplification of the regulatory framework, which increasingly hindered the conduct of medical and biological research in the field of genetics. "The regulations pertaining to this area have now been largely compiled into a single Act, and researchers now have to relate mainly to one authority when applying for approval of research projects. This authority consists of the Regional Committees for Medical and Health Research Ethics (REK)."[21]

[17] The Biobanks and Health Databanks Act No. 110/2000 as amended by Act No. 27/2008, No. 48/2009 and No. 45/2014. Available at: https://www.government.is/media/velferdarraduneyti-media/media/acrobat-enskar_sidur/Biobanks-Act-as-amended-2015.pdf [Accessed 07.09.2023].

[18] The Cultural Heritage Act No. 80/2012. Available at: https://www.althingi.is/altext/stjt/2012.080.html [Accessed 07.09.2023]. (In Icelandic).

[19] The Health Research Act. 8 October 2020. Available at: https://www.forskningsetikk.no/en/resources/the-research-ethics-library/legal-statutes-and-guidelines/the-health-research-act/ [Accessed 07.08.2022].

[20] Summary of the Official Norwegian Report NOU 2005:1 — Good Research, Better Health. Available at: https://www.helsetilsynet.no/globalassets/opplastinger/english/nou_2005_1_english-summary.pdf [Accessed 07.08.2022].

[21] The Health Research Act. 8 October 2020.

Regulation of scientific research due to the peculiarities of this type of activity is a most difficult task for legislators. The Norwegian Health Research Act establishes minimum general requirements for the organization and content of research. Content analysis inevitably leads to ethical issues that prompted legislators to introduce the concept of ethically based research. The functions of the REC include the study of possible ethical violations and a "standard assessment of the research ethics of the project" in the form of preliminary approval of the latter. "Ethical standards can be established in writing (for example, the ethical rules of professional associations and the Helsinki Declaration), stem from individual decisions taken by the ethical bodies of professional associations, supervisory authorities, the REC, the National Committee on Ethics of Medical Research and Health Research. (NEM) or the courts, or follow from principles generally recognized by society as a whole or by professionals. "Ethical standards may be established in writing (for example the ethical rules of professional associations and the Declaration of Helsinki), ensue from individual decisions taken by the ethical bodies of professional associations, supervisory bodies, REK, the National Committee for Medical and Health Research Ethics (NEM) or courts of law, or ensue from principles that are generally recognised by society in general or the professions."[22]

VIII. The Importance of Bioresource Collections for the Preservation of the Achieved Level of Biodiversity: The Contribution of Northern Europe

Biobanks specializing in human genetic data are not the only type of bioresource collections. Although the legal and administrative regulation of their activities plays a much smaller role in the legal development of the Nordic countries, the importance of this branch of genomic research and the use of genetic technologies cannot be underestimated. For example, Marte Qvenild (2008) compares the global seed storage created by the Norwegians on the island of Svalbard with the "Noah's Ark." The meaning of this allegory is clear: in the event

[22] The Health Research Act. 8 October 2020.

of an anthropogenic or natural global catastrophe, this repository will provide the humanity with hope for at least a partial restoration of the biodiversity available today. It similar to the acquisition by medieval Europeans of ancient manuscripts in Arabic translation, and then in the original, made possible a cultural Renaissance and the birth of modern Europe.

It all began in 1984, when, on the initiative of the Scandinavian Genome Bank (NGB), an abandoned coalmine in the Arctic Archipelago was converted into a repository for duplicate seed collections from Northern European countries. For this purpose, a large roomy metal container was used, inside which seeds packed in sealed glass ampoules and placed in wooden boxes were stored. The increasing technological capabilities resulted in the storage conditions improvement: aluminum bags have replaced glass ampoules; their "germination" is regularly checked. The importance of this enterprise is increasingly becoming more recognized: the growing fears of another great extinction under the influence of global warming and other catastrophic phenomena of both man-made and natural nature add up to the fear born of the threat of nuclear war.

The creation of the repository has given rise to many legal and political problems discussed in the Food and Agriculture Organization of the United Nations (FAO). The debates in the Commission on Genetic Resources for Food and Agriculture, held at the Tenth Regular Session of the Commission on Genetic Resources for Food, Agriculture in Rome on November 8–12, 2004 was completed with the "CGRFA-10/04/REP" Report that highlighted the difference in the approaches applied in developed and developing countries. While developing countries wanted free access to plant genetic resources, most developed countries and the seed industry wanted to strengthen the exclusive rights of breeders to improved plant genetic material.

By locating an "international" storage bank in a developed country without legal clarity regarding the ownership of the material, the initiators created ideal conditions for a conflict of interest. As M. Qvenild notes, FAO and the International Board for Plant Genetic Resources (IBPGR) hastened to guarantee "unlimited access of depositors to their materials stored in Svalbard." They stressed that "every germ

plasm deposit should remain the property of the Depositor... and will not be opened or used by any other party without the consent of the Depositor. Developing countries have already had experience of how plant genetic material collected in their countries was improved and protected by intellectual property rights by the seed industry, which led to blocking the country of origin from obtaining financial benefits or even preserving the freedom of use of the material in some cases" (Qvenild, 2008, p. 113). This episode once again highlights the complexity of the value basis of the legal regulation of the turnover of genetic materials related to food and agriculture. The experience of the Nordic countries shows how harmful the influence of economic interests on the sphere of science and scientific knowledge can be. Issues of ethics and politics are inextricably linked with the development of law, but in this case, this connection is especially relevant.

Apparently, then the scientific community seemed to cope well with such problems within the framework of the existing scientific traditions and research practices. Indeed, the organization of scientific expertise has always been regulated; there were reviewers, opponents, academic councils, and scientific supervisors, departments in universities and departments in research institutes. If there was an ethical aspect in assessing the relevance of the topic or the scientific novelty of the results obtained, it was more likely to appear when discussing the means chosen by the researcher to achieve the goals set than in discussions about the goals themselves.

IX. Conclusion

The experience of the evolution of the Institute of the Ethics committee is most valuable for the development of the system of legal regulation of genomic research and the use of genetic technologies. The movement towards mutual harmonization of national systems of legal regulation of biobanks in the Nordic countries led to the creation in 2014 of a single body — the Nordic Committee on Bioethics. The reasons here were the motives of the similarity of the legal systems of the five countries of the region and the resulting awareness of the similarity of the problems facing the legislators of these countries on the

way to their integration into the common legal space of the European Union. The annual bulletins published by the Committee allow for a comparative analysis of national legislation on the following items: assisted reproduction, preimplantation genetic diagnostics (PGD) and genetic screening (PGS), abortions, prenatal diagnostics and/or screening, organ and tissue transplantation, embryo research, cloning, human clinical trials, biobanks, etc. The discussion of the legal status of the Council of Europe Convention on Biomedicine and its additional Protocols is highlighted separately.[23]

A French journalist, during an interview, asked M. Heidegger if he was ready to write about "Ethics" that, in accordance with tradition, would be interpreted as a doctrine of action? "Ethics?" the German philosopher asked. "Who can afford it today and on behalf of what authority to offer it to the world?" (Palmier and Towarnicki, 1969). From the point of view of classical philosophy and theory of law, ethics and law are separate social regulators, although they are closely related to each other and ideally should not conflict with each other. Meanwhile, in everyday life and in diverse social practices, they often diverge, resulting in incessant philosophical discussions about the relationship between law and morality. However, with the advent of ethical committees, the question of their ontological status arose, which gave rise to three different concepts explaining the nature and essence of this phenomenon. The first concept, which could be called the "right regulator," interprets the ethics committee as a special legal institution, where the source of law is the decision of a qualified assembly, whose activities are regulated by law. The second concept, conventionally referred to as the formula "together with the law," interprets the ethics committee as a social institution whose decisions are complemented by the actions of laws and ensure their qualified application. And finally, the third concept, built according to the "instead of law" formula, means abandoning the idea of legal regulation of a certain type of decisions taken during scientific research, clinical trials and even medical practices due to the lack of such regulation. In this case, we are talking

[23] Legislation on biotechnology in the Nordic countries. An overview 2022. Available at: https://www.nordforsk.org/2022/legislation-biotechnology-nordic-countries [Accessed 07.09.2023].

about replacing the legal regulator with some other social regulator, in particular, bioethics. Among the advantages of the latter is the fact that bioethics differs qualitatively from traditional ethics in that it does not appeal to any authority or any tradition, but, consistent with law and morality, represents a social technology for making the best decisions from both an ethical and a legal point of view.

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Information about the Author

Vladimir I. Przhilenskiy, Dr. Sci. (Law), Professor, Department of Philosophic and Socio-Economic Disciplines, Kutafin Moscow State Law University (MSAL), Moscow, Russian Federation

9, Sadovaya-Kudrinskaya St., Moscow 125993, Russian Federation

vladprnow@mail.ru

ORCID: 0000-0002-5942-3732