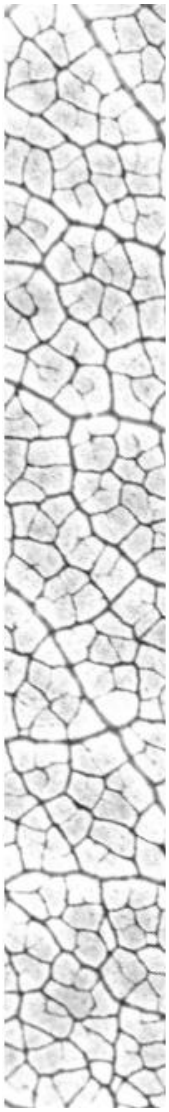

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Legal problems of forming genetic information banks in Russia

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Abstract
The topicality of the research topic is due to the expansion of national and interstate initiatives on genome research which have significant potential for human health research. This scientific article is aimed at revealing the problems of legal regulation of formation of genetic information banks and elaboration of concrete proposals on improvement of modern legislation. The methods of study of this problem are: empirical methods of comparison, interpretation; theoretical methods of formal and dialectical logic; private scientific methods: comparative law and method of interpretation of legal norms. The article presents conceptual approaches to determining the legal nature of genetic information banks; reveals the specific features of genetic information, which determine the mechanisms for protecting genetic data; makes recommendations for the development in the legal regulation of the relations under study. The materials of the article represent practical value for scientists and practitioners involved in the legal support for the circulation of genetic information. The novelty and originality of the research consists in the fact that it considers the concept and goals of formation of genetic information banks, types of genetic information structured in them and existing problems of legal support for databases.

Keywords: genetic testing, genetic information, personal data, genetic information banks, biobanks, informed consent, information deidendification

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INTRODUCTION

National and interstate initiatives in genome research create huge amounts of genetic data which have significant potential for human health research. Genetic data banks are essential resources and platforms for biomedical research that serve fundamental, translational (Kolbin, Gapeshin & Malyshev, 2014) and clinical research projects (Herpel et al., 2010).

Biobanks for research purposes have been created in Russia since 2012. Among them, in particular, the Biobank of the Almazov NMRC, the National BioService, the Biobank of the St. Petersburg State University (St. Petersburg State University), the Biobank of the Lomonosov Moscow State University and etc (Reznik et al., 2016). However, the total volume of samples in Russian biobanks still does not exceed one million. With the support of the Ministry of Health of the Russian Federation, the National association of biobanks and biobanking specialists (NASIBO) has been established since 2018 in order to solve the tasks of creating a full-fledged network of biobanks, depositories and collections of biomaterials in the country with 21 legal entities becoming members. Its goal is to unite the efforts of specialists in the field of biobanking network development in Russia, to provide specialized and educational services in the field of biobanking as well as to promote scientific and practical projects, programs related to the use of funds and infrastructure of biobanks.

Genetic information banks are evolving from disparate databases created by individual research teams into central elements of a single research infrastructure and should now be considered as a source of information for the development of biotechnology, health care and life science research (Assabler & Zatloukal, 2007).

Russian President V.V. Putin, speaking at a meeting on the development of genetic technologies in Russia, put forward the idea of creating the Russian National base (Putin suggested creating a national database of genetic information, 2020) of genetic information which may contain systematized information about the human genome available to domestic scientists and would allow

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to achieve significant progress in the formation of genetic technologies in the long term.

As a result of expansion of subjects' activity on formation of genetic information banks, we can observe collision of various general theoretical positions related to their purpose and use in scientific and medical research; assessment of risk efficiency, control, improvement of management system, certification and standardization of genetic information banks (Catchpoole, 2017).

As our research shows, the control of the use of this data is currently a topical problem which is directly related to the protection of fundamental human rights and freedoms, the right of individuals to privacy of personal information. All this requires a detailed elaboration of the legal framework for the creation and use of genetic data banks.

Based on the analysis of the legal nature in genetic information banks, three key issues can be emphasized: 1) the concept and objectives of the creation of the examined data sets; 2) the legal regime of the genetic information bank; 3) problems of ensuring confidentiality of the information systematized in the genetic information bank as well as mechanisms for protecting such information.

METHODOLOGICAL FRAMEWORK

Answering the given questions, it is necessary to determine the distinctive features characterizing the banks of genetic information.

As a rule, genetic information banks are elements of more general research structures - biobanks which in addition to data contain collections of bio samples that are their carriers.

The Organization for Economic Cooperation and Development (OECD) defines a biobank as «the aggregate of biological material and associated data and information stored in an organized system and used for the needs of an entire population or a significant portion thereof» (OECD, 2006).

Europe's largest Biobanking and BioMolecular Resources Research Infrastructure (BBMRI), which brings together 20 countries, defines a biobank as a collection of all types of human biological samples (blood, tissue, cells or DNA) pertaining to data samples as well as other biomolecular resources that can be used in medical research (What is biobanking, 2020). This broad definition includes both large-scale national and international research resources as well as small collections of biological samples and related data from medical research institutes, cancer centers and hospitals.

There is a point of view according to which it is necessary to distinguish a biobank from storage of human tissues created for diagnostic or clinical purposes and also commercial biobanks (Cambon-Thomsen, Rial-Sebbag &Knoppers, 2007). It is proposed to limit the use of biobank for research purposes only.

Such ambiguity in the definition of a biobank makes it difficult to establish an ethical framework to regulate the behavior of subjects, to establish an effective mechanism for legal regulation in relation to the formation of genetic information banks.

We should understand what genetic information is generated in a bank in order to understand this issue in detail. The analysis shows that European legislation distinguishes between non-coding DNA segments and coding DNA segments (Brassolov, Chubukova & Mikurova, 2019).

Non-coding DNA segments are designed to identify a person, so they are also called genetic fingerprints. Genetic information databases created for forensic research only operate with non-coding DNA segments. The only purpose of this type of genetic information processing is to identify a person, not to study his or her physiological, morphological, hereditary characteristics.

Today, on the basis of non-coding DNA elements, a genetic passport is created. This is a document containing information on genetic personality of a person. The information contained in the passport will be universal and sufficient to identify a specific individual. Molecular genetic examination is often called genetic fingerprinting. The encoding of genetic information used in a passport does not contain information about human features, physiological and mental features as well as about hereditary diseases. By matching the data obtained by analyzing any biological material with the information specified in the genetic passport, a geneticist will make an accurate conclusion about whether the biological material belongs to a person according to his or her genetic passport. It is this type of structural (internal) information that should find regulation in the legislation on personal data.

Let us consider the main goals of creating genetic information banks and the types of genetic data used in them.

In order to prevent and solve crimes, identify and locate the perpetrators, as well as identify unidentified corpses, in many countries specialized state information resources are being created - National Automated Register of Genetic Prints (Fichier national automatisé des empreintes génétiques, FNAEG) in France, National DNA Database (National DNA Database, NDNAD) of England and Wales and etc. In our country, in accordance with the Federal Law № 242-FZ of 03.12.2008 «On state genome registration in the Russian Federation» (Federal law, 2008), a federal database of genomic information, the Federal Automated Information System for Genomic Information Processing, was also created.

The use of genetic information for clinical and diagnostic purposes may be related to obtaining a so-

called «genetic passport» which is a detailed genetic test that determines the risk of diseases in a person and probability of having children with hereditary disorders. Genetic data is present in every cell of our body, so almost any biological material can be used for the analysis such as a tiny sample of saliva, blood or any biological fluid.

The use of genetic passports will promote the development of personalized medicine (Paltsev, 2011), as doctors will be able to predict the risks of disease in an individual, to preserve the health of the person and his descendants, to determine his origin on the basis of data on several generations.

Even today, children in Russian maternity hospitals are screened for five hereditary diseases. DNA of newborns is tested for adrenogenital syndrome, galactosemia, congenital hypothyroidism, cystic fibrosis, phenylketonuria. And this list is planned to be extended up to 23 screened diseases (Genetic passports will appear in Russia, 2020).

The analysis shows that genetic passporting of the Russian population will allow to define hereditary diseases among people; to reveal predisposition to cancer and other fatal diseases, to start treatment in due time; to keep health of newborns; to carry out correct treatment of the diseased taking into account their individual features; to reveal criminals; to identify remains of the dead. It is thought that in the future individual genetic passporting will need to be improved. For these purposes it will be necessary to develop not only passporting methods and technologies used but above all legislation.

Many experts rightly believe that protection mechanisms for these species of biobanks will require increased control and supervision by the state and specially created Ethics Committees. The use of bio-samples and related data will lead to the need to maintain the necessary balance between the interests of the state in health care, scientific research and the protection of public interests such as the confidentiality of personal information (Graham, Molster & Baynam, 2014).

A slightly different viewpoint exists with respect to data protection in genetic information banks used for research purposes which systematize usually coding DNA segments. Thus, some specialists point out that in the National Genetic Information Database genetic data will be presented in the form of non-personified (anonymized) data and it will not meet the features of personal data because on their basis it will be impossible to identify the person (Interview with associate professor of the department of civil law of the national research Tomsk state University, 2016). This makes it possible not to apply the legislation on personal data and its requirements on information protection to genetic information banks.

In our opinion, this statement is invalid for the following reasons.

First, given recent advances in genetics, the difference between encoding and non-coding parts of DNA has become less pronounced. DNA analysis methods are developing rapidly. This improvement in genetic methods has led to the fact that some of the DNA segments that make up the French national FNAEG base have been able to identify hereditary morphological, physiological, pathological, ethnic and other characteristics of individuals. Geneticists have demonstrated that at least three of the segments registered with FNAEG from the beginning are significant markers because they are genetically linked to the genetic disease (CCNE, 2007). These discoveries led to the European Union's decision in 1997 to ban the use of markers in the exchange of DNA results if scientific discoveries showed that it contains information about hereditary characteristics.

In addition, recommendations have been made that Member States should destroy the DNA test results they received if they are found to include information on specific hereditary characteristics (Résolution, 1997).

Second, attention should be paid to the fact that genetic testing is becoming increasingly available. The tests analyzed may have different purposes, such as confirmation the diagnosis or detection of diseases in individuals as well as the risk of disease progression, establishing kinship, determining ethnic or genealogical origin, checking «genetic compatibility» between the two individuals and so on. The growth of genetic research is the result of a significant reduction in financial costs and it allows us to talk about the emergence of a real market for genetic data.

The first economic models for the turnover of biological samples and related genetic data have already been implemented by transnational companies. The commercial use of genetic science raises not only serious ethical issues but also threatens the biological security of an individual, whole peoples and nations.

Third, de-identification, which applies to different types of data, including genetic data, carries significant risks. Recent studies in the United States have shown that some de-identified data can be reidentified including information with a medical focus. Accordingly, as long as the de-identified data can be reidentified, the confidentiality protection afforded by the de-identification is lost (Simson, 2020). Thus, the decision on how the data will be de-identified should be made in conjunction with a conclusion on how the de-identified data will be used and published as the risk of reidentification is difficult to objectively assess and analyze. The essence of such risk is the ability of third parties to draw conclusions about a particular group of people or specific individuals and to influence them with the knowledge of certain confidential information.

These discoveries allow to conclude that genetic information as a whole (and not only the part of it that allows to identify a person directly) should be stored and processed under strict supervision of public professional organizations (corresponding ethics committees) as well as the state.

RESULTS

The bank of genetic information is proposed to be understood as a set of systematized genetic information and data used for forensic, clinical-diagnostic and research purposes.

We believe that citizens' genetic data should be stored in genetic information banks created for research purposes in an impersonal form that does not allow identifying a specific individual. The decision as to how the data will be de-identified should be made in conjunction with the conclusion as to how the de-identified data will be used and published as the risk of re-identification is difficult to assess and analyze objectively.

Genetic data should relate to information that is specially protected by the state. Uncontrolled circulation of genetic information can lead to unforeseen negative consequences. For example, the threat of national (ethnic) biological weapons has recently emerged. In some cases, the leakage of investigational data abroad may pose a threat to a country's national security (Chubukova & Rassolov, 2020).

The possession by countries of genetic weapons in the form of modified genes, viruses adapted to a particular gene, is a threat to the biological security of the state. Some experts believe that DNA samples may be used to develop vaccines or create biological weapons (Key to the genetic code: why the US military buys Russian biomaterials, 2020).

Although the concept of a biobank is treated differently by different authors, one of the main requirements in establishing a legal regime for the formation of genetic information banks is to address ethical and legal issues related to patient consent, security of personal data circulation and their protection (Budimir, Polašek & Marušić, 2011).

DISCUSSIONS

In many countries, including Russia, the legislator went the way of recognition for genetic information of the special legal regime of personal data.

Taking into account the actively developing process of digitalization as well as the dynamics of new technologies in the private sector, the Committee of Ministers of the Council of Europe adopted on 27.03. 2019 new Recommendations CM/Rec (2019) on the protection of health-related data (Recommendation CM/Rec, 2019). These Recommendations limit the purposes of genetic data processing to the diagnosis and treatment of the individual (or a member of his biological family) as well as to scientific research.

As well as the European General Data Protection Regulation (GDPR) (General Data Protection Regulation, 2020), the Recommendation establishes that genetic data should be processed in the framework of a research project only if the data subject has given his consent. In exceptional cases, the processing of medical data for scientific research can be carried out without the consent of the data subject. However, these cases should be clearly established in the national legislation of the EU Member States and provide adequate safeguards to protect the fundamental rights and freedoms of the data subject. Such safeguards should ensure the principle of data minimization which implies that the amount of personal data collected should be consistent with the stated purposes and not exceed them; it should include technical and organizational measures to ensure the confidentiality of genetic data and to protect the rights of the data subject.

It should be noted that in the field of scientific research, there are often problems associated with determining the purpose for research, as well as the ability to inform the person whose data is analyzed in the framework to the research, about the conditions to research and the content of the subject's consent to the processing of personal data.

The problem of goal setting is that at the time when research projects are launched, their organizers and researchers are not always able to define concretely and clearly the objectives of different research areas as required by the general provisions of the European GDPR. For example, it is initially possible to define only the subject areas of research or the goals for individual parts in a research project. In these cases, in European practice, there is a requirement for a preliminary evaluation of a scientific project by a competent independent body (e.g. an ethics committee) which analyses the conditions under which health-related data is processed and draws conclusions on the compliance of the research project with recognized ethical standards. Those who consent to the processing of data should be made aware of the compliance for the project conditions with recognized ethical standards.

In general, the data to be processed must be impersonal, but not always the purpose of the scientific research also makes it possible to meet this requirement. If it is not possible to impersonalize the data, a pseudonymization procedure must be carried out with a trusted third party. Pseudonymization of data involves the use of a mechanism of identification for the subject by which it is impossible to identify him without the use of additional information stored by the trusted person (Stolbov, 2017).

In cases where an individual refuses to participate in a research project, his or her data processed in the framework of scientific research should be destroyed or

impersonalized in a way that does not jeopardize the scientific validity of the research itself and the data subject should be informed accordingly.

Information about ongoing scientific projects, as well as their results, should not be published in a form that allows identifying a person, except if the data subject has consented to this, or if the law allows such publication, provided that the public interest in the publication of data prevails over the private interests of the citizen. For example, cases of publication the health information about volunteers who are testing experimental vaccines against new forms of diseases, such as the COVID-19 coronovirus.

All these features of scientific research required a review to the General requirements for the subject's consent to the processing of his data. Today among genome researchers there is a consensus on the fact that only «broad consent» is ethically and legally acceptable form of consent (Broad Consent for Future Research: International Perspectives, 2020).

«Broad agreement» means that a research participant expressly agrees that his or her data and/or samples will be used for a range of future research projects that are subject to control and ongoing oversight by specialized regulatory bodies (e.g. where research is approved and monitored by ethics committees).

The Russian legislation on personal data (Federal law, 2006) at the moment does not contain all the novelties of this European Regulation. In particular, this applies to such rights of the personal data subject as the right to transfer data between the operators, the right to obtain a copy of the data and the right to notify the subject when his personal data are changed or deleted.

CONCLUSION

So, the undertaken analysis allows to draw conclusions about the main directions of improvement in modern legislation on the formation of genetic information banks in the Russian Federation.

Firstly, the analysis showed that genetic information banks are the systems of structured information storage. In recent years, they have become an integral part of personalized medicine and provide progress in understanding the mechanisms of disease development, development of methods for prevention, diagnosis and treatment.

Secondly, the studied banks of genetic information are created for different purposes, such as research, clinical-diagnostic and forensic.

Thirdly, legal support of genetic information banks is predetermined by the volume of genetic data structured in such an array of information. We believe that it is necessary to further harmonize the Russian legislation on personal data with the European legislation and the provisions of the European Regulation on Personal Data Protection (GDPR).

Fourth, conducting medical scientific genetic research requires the use of broad consent of the person participating in the research. «Broad agreement» means that the research participant expressly agrees that his/her data and/or samples will be used for a range of future research projects that are subject to external and ongoing oversight (e.g. where research is approved and monitored by ethics committees). The «broad agreement» should define the categories of data processing methods, the safeguards to mitigate the risks associated with these methods and the categories of potential data recipients.

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