ABOUT SOME ISSUES OF LEGAL REGULATION OF THE STATUS OF PARTICIPANTS INVOLVED IN GENOMIC RESEARCH

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Continuous development of social relations implies the need in constant improvement of primarily legislative regulation so that it could adapt to the current realities in the society and country. This assumption is true both with regard to the legal regulation of the status given to participants of genomic research, as this relatively new area of social relations embraces both public, and private interests. In this respect, legal regulation should consider certain principles such as the balance of public and private interests, protection of human rights and freedoms, protection of sensitive data by the law, protection of the national interests, etc. Nevertheless, normative legal regulation of the status of genomic research participants in the Russian Federation is not complex in nature yet. Thus, it fails to result in development of this area of social relations and ensuring the rights, freedoms and legitimate interests of the mentioned persons. It is necessary to settle the issue about the boundaries of the allowed behavior, rights, obligations, guarantees and liability of genetic research participants. It seems to be appropriate to develop a complex federal law about the legal status of genetic research participants in the Russian Federation. A general approach to arranging complex legal regulation in this field consists in systematization of the existing legal regulation considering legislative regulatory activity of the discovered issues in the field of using genetic technologies and conducting genome research. During the regulatory control, it is necessary to reflect common moral and ethical principles and standards of medical and genetic research.

Keywords: human genome, genomic research, legal status, legal regulation, patients, research scientists

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Received: 22.04.2022 **Accepted:** 27.05.2022 **Published online:** 30.06.2022

DOI: 10.24075/medet.2022.046

О НЕКОТОРЫХ ВОПРОСАХ ПРАВОВОГО РЕГУЛИРОВАНИЯ СТАТУСА УЧАСТНИКОВ ГЕНОМНЫХ ИССЛЕДОВАНИЙ

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Непрерывное развитие общественных отношений влечет за собой необходимость постоянного совершенствования, в первую очередь, законодательного регулирования, чтобы оно отвечало сложившимся в обществе и государстве реалиям. Данное утверждение является верным и в отношении правовой регламентации статуса участников геномных исследований, поскольку данная относительно новая сфера общественных отношений сочетает в себе как публичные, так и частные интересы. В этой связи правовое регулирование должно учитывать такие принципы, как баланс публичных и частных интересов, защита прав и свобод человека, защита охраняемой законом тайны, обеспечение национальных интересов государства и т. п. Однако до последнего момента нормативное правовое регулирование статуса участников генетических исследований в Российской Федерации не имеет комплексного характера, что не способствует развитию данной сферы общественных отношений, а также обеспечению прав, свобод и законных интересов отмеченных лиц. Необходимо посредством права решить вопрос о границах дозволенного поведения участников генетических исследований, их правах, обязанностях, гарантиях и ответственности. Представляется целесообразной разработка комплексного федерального закона о правовом статусе участников генетических исследований в Российской Федерации. Общий подход к выстраиванию полноценного правового регулирования в данной сфере видится в систематизации сложившегося правового регулирования с учетом необходимости законодательной регламентации выявленных проблем в сфере использования генетических технологий и проведения геномных исследований. Также при осуществлении такого нормативного регулирования должны получить отражение общепризнанные морально-этические принципы и нормы проведения медицинских, а также генетических исследований.

Ключевые слова: геном человека, геномные исследования, правовой статус, правовое регулирование, пациенты, ученые-исследователи

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Статья поступила: 22.04.2022 **Статья принята к печати:** 27.05.2022 **Опубликована онлайн:** 30.06.2022

DOI: 10.24075/medet.2022.046

Modern genomic research provides access to previously inaccessible areas of disease prevention and treatment, development of the latest methods of clinical diagnostics, family planning, crime fighting, etc.

Genomic research, however, directly touches upon fundamental human rights (human dignity, protection of privacy and health, etc.). So, observance of these rights needs particular attention. It is also necessary to develop the respective legal acts. This legal regulation should consider the values that are significant both for the society, and the country such as the balance of public and private interests, necessary development of Russian science, compliance with rights and freedoms of a person and a citizen, protection of legally guarded confidential data, etc.

Normative legal regulation of social relations in Russia can currently be of a fragmented nature, because it is ultimately about the issues of state genomic registration, gene engineering, and genomic (genetic and molecular) expertise.

In this connection, the issue about the balanced interests of different participants of genetic research and selection of an optimal model of legal regulation of these social relations might also be relevant. On the one hand, the rights, freedoms and interests of patients and their relatives must definitely be respected. On the other hand, excessive restrictive regulation

might significantly complicate and actually slow down development of the Russian genetic science, which is now inferior to that in other countries (USA, Great Britain, Germany, France, etc.) as it is.

Thus, a balanced option needs to be selected that would ensure both patients' rights and freedoms in accordance with international standards, and freedom of scientific activity. This can be done by reducing an unreasonably vast number of administrative barriers, just like they did it in the USA, a world leader in genetics.

A huge potential of using genomic research results makes it relevant to adopt the respective normative legal framework and state programs (Presidential Decree of the Russian Federation as of November 28, 2018 No. 680 'Concerning development of genetic technologies in the Russian Federation', Government Resolution of the Russian Federation as of April 22, 2019 No. 479 'Concerning approval of the Federal scientific and technological program of genetic technology development for 2019–2027', etc.)

Along with handling the issues of genetics innovative development and use of genetic research results in different economic sectors (agriculture, food supply, healthcare, etc.), there exists an objective need in legal regulation of the status of genetic research participants. This particularly concerns the legislative establishment of the boundaries of allowable behavior of genetic research participants, their rights and obligations, guarantees and responsibilities.

RESEARCH RESULTS

It appears that genetic research participants can be subdivided into two groups.

I. Persons, whose genetic materials is used for the purpose of the genetic research.
   1. Patients are people who provide consent to use of their genetic material during genetic research.
   2. Persons having a genetic relationship with patients.

II. Subjects involved in organization or direct conduction of the genetic research.
   1. Organizations.
   2. Research scientists.
   3. Medical personnel.

The legal status (rights, obligations, guarantees and responsibility) of the mentioned participants of genetic research should be reflected in the respective legislative regulation, for instance, by way of adopting a separate federal law about the status of genomic research participants. In this respect, the Russian legislator should not only follow the widely accepted international standards of how medical — including genetic — research should be conducted, but also pay attention to the existing models that legally regulate the status of genetic research participants. A basic model should be selected while observing the constitutional values, and accepting the need to develop genetic research in Russia.

It must be noted that the legal status of patients as participants of any medical and scientific research is based on interrelated provisions of the Constitution of the Russian Federation as of 1993 and international rules (Convention for biological diversity as of June 5, 1992, Convention for the protection of human rights and fundamental freedoms as of November 4, 1950, Convention for the protection of human rights and dignity due to the use of biological and medical achievements: Convention on human rights and biomedicine as of April 4, 1997, etc.) [1].

The following provisions of the Constitution of the Russian Federation should be noted: the ultimate value of a person, his/her rights and freedoms (art. 2); equal rights, freedoms and responsibilities for all citizens (part 2, art. 6); protection of human health and labor by the state (part 2, art. 7); the principle of ideological diversity which means that it's impossible to pose restrictions or obligations on citizens depending on any ideology (part 1, art. 13); protection of human dignity by the state, prohibition of tortures, violence, other cruel, inhuman or degrading treatment or punishment, or being subjected to medical, scientific or other experiments without voluntary consent (art. 21), protection of privacy, personal and family confidential data, protection of honor and good name (part 1, art. 23); prohibition to collect, keep, use and distribute data about a person's private life without his/her consent (part 1, art. 24); warrant of judicial remedy of rights and freedoms (art. 46), etc.

The list of constitutional rights is open. This guarantees that it is impossible to deny or restrict other common rights and freedoms of a person and citizen.

Particular attention should be paid to part 2, art. 21 of the Constitution of the Russian Federation. It states that nobody can be exposed to medical, scientific or other research without voluntary consent. Human dignity is of subjectively legal and objectively legal nature. On the one hand, the country is prohibited to willfully infringe on an individual's autonomy; on the other hand, the country needs to create a system of justice excluding infringement on personal dignity on the part both of the country, and individuals.

In a number of its decisions (Decision as of Febr. 18, 2000 No. 3-П; Orders as of Jan. 29, 2009 No. 3-О-О, as of Sept. 29, 2011 No. 1063-О-О), the Constitutional Court of the Russian Federation noted that in accordance with some interrelated provisions of the Constitution of the Russian Federation (part 4, art. 29; part 1, art. 23; part 1, art. 24), it is prohibited to collect, keep, use and distribute the data associated with violation of constitutional human rights to privacy, private and family confidential information. In this regard, it needs to be considered that genomic data completely conforms to the features of personal data established by the federal legislation on personal data. Thus, we need just to define an optimal legal regimen of personal data that should be used in relation to genomic information about citizens.

Moreover, in some decisions of the Constitutional Court of the Russian Federation it has also been noted that as human rights (part 3, art. 17 and part 3, art. 55) can be limited based on the federal law of certain constitutional value protection, realization of the constitutional right to the information that affects the private life of other persons should be regulated in the manner established by the law; the Constitution of Russia accepts that a special legal regimen -including the regimen of restricting free access to the third parties — can be used with regard to some data.

We assume that people with genetic relation to the patients should be considered as participants of genetic research with a special status. As relatives are genetically related to patients, genetic research and obtaining the respective information will impact their rights and legal interests. This provision is based on part 3, art. 17 of the Constitution of the Russian Federation stating that exercising human and civil rights and freedoms should not violate the rights and freedoms of other people. Accordingly, when exercising the rights and freedoms of his own, a citizen (patient) must not violate the rights and freedoms of other people or genetic relatives, in particular (for instance, a right to privacy, personal and family confidential data).

Ensuring the compliance with the regimen of personal data of the persons whose genetic material is used for genetic research remains the cornerstone of the issue of legal regulation. It is assumed that a legislator needs to consider an increased level of personal genetic data legal protection. There are several reasons for that.

First, genetic data about the patient directly influences the rights of his/her genetic relatives, including the minor ones, as it carries certain information about their health, mental condition, typical behavior [2: 186–188].

Second, genetic material analysis enables effective identification of a person (and his/her genetic relatives) which is actively being used to combat criminal activities [3].

Third, the issue of creating unauthorized genetic data banks compiled by way of uncontrolled collection of their genetic material (without their voluntary consent) is getting more urgent these days. For instance, the results of citizens' genetic research are of major interest for employers and insurance companies, as it can provide data about possible human genetic predisposition, including predisposition to a certain disease, and cognitive capacities [4: 69–70].

Thus, some companies can already use these data upon recruitment, promotion, termination or when distributing tasks and solving insurance issues.

At the same time, genetic data can't be utilized to precisely predict a person's future, as 'the increase of an individual risk by two or five times even in case of high population risk (for instance, 1/1000) doesn't mean that the subject will be affected by that disease. Consequently, even under GWAS conditions, it can now be only determined whether a person relates to the group of high risk for a multifactorial disease; but it is not possible to provide sound prognosis about implementation of this risk for a certain individual' [5: 83]. In this respect, a person with no diseases can be a victim of discrimination on genetic basis just based on a probability of their occurrence, which is unacceptable in the modern legal democratic country.

Fourth, genetic information is a specific type of personal data. It requires improved measures of state protection because genetic data (unlike biometric data, residential address) identifies and characterizes a wide range of persons who have a genetic relationship with the patient, including subsequent generations. Thus, the data will to some extent be related to the patient's descendants and genetic relatives. That's why, theoretically speaking, it will be indefinite in nature.

The Russian legislator should, tailored to the particular situation, set forth by legal acts and guarantee compliance with the rules of conducting genetic research and using the obtained results, that are widely accepted by the leading countries on the scientific and legislative levels, genetic data confidentiality and prohibition of its transfer to the third persons. In addition to that, it is also necessary to obtain consent of close (and far) relatives with genetic relationship to the patient to authorize the research and use the obtained results for legitimate purposes.

Regulation of the legal status of the subjects who conduct genetic research should also include such elements as rights, obligations, guarantees and responsibility. Considering a complex nature of these social relations and particular value of genetic data about a human being, the principal activities of legislative regulation of the subjects' activity should be as follows:

1) ensuring legitimacy and transparency of the noted research activity;
2) establishing the corresponding obligations, and mechanisms of holding legally responsible to observe patients' rights and freedoms;
3) enhancing development of genetics, state support of research aimed at improvement of citizens' health and protection of national interests.

There is no legal certainty in the issue of legislative regulation of the nature, methods and standards of genetic research in the country, prevention and elimination of genetic discrimination. It can be asserted that Russia is on the path of building a complex model of legal regulation of carrying out genetic research.

The acting Russian regulatory acts and judicial practice neither establish the content of human rights in the area of genomic research, nor state specific legal guarantees; the human genome is not considered as a legal element to protect health and provide medical aid.

It is possible to agree that the principal modern threats in the sphere of genomic data handling faced by Russia until now can include cost-intensive nature, unauthorized access, errors, massive screenings, irresponsible collection and irresponsible storage of genomic data [6: 136]. Given that determining position of one gene in a human genome enables errorless identification of the only person out of 10 billion others, conducting genomic research sets certain tasks in the sphere of protection of personal data, private life, medical, family and other law-protected confidentiality [7: 183].

Another issue is to establish liability for committing offences in the regarded area of social relations. On the one hand, causing harm to patients' health by genome editing or gene therapy is not permitted and must include the use of the corresponding measures of legal (disciplinary, administrative, criminal, civil) liability to those guilty. On the other hand, it is necessary to consider the circumstances in every particular case and bear in mind that conducting genetic research is difficult. Though medical mistakes are almost inevitable when working at any innovative projects in the sphere of genetic technologies, legal regulation at various levels should ensure development of open, clear and substantiated rules of behavior for genetic research participants.

Moreover, after genomic research has been conducted, the issue of legal protection and support of the genomic information obtained becomes relevant. Analysis of the acting criminal and administrative legislation of the Russian Federation and judicial practice allows for the conclusion that using legal liability in this area is highly problematic as there are no specific standards devoted to genomic data protection, human genome editing, prohibition to transfer genomic data to the third parties, etc. Meanwhile, the administrative regulation addresses only responsibility for violation when using genetically modified organisms (GMO) or GMO-based products [8: 65–66].

DISCUSSION RESULTS

It is necessary to accept that distance between specialists engaged in genetic and genomic research does not promote development of unified ethical requirements [9: 56]. Well-established requirements in the area of genetic consultation while revealing orphan (rare) diseases are incompatible with a complex set of ethical issues that arise in genomic counselling, during which the patient's and his/her family's interests regarding both protection of the person's general rights and interpretation of personal data obtained during the research are combined [9: 57].

It seems that the discussions that arise in science in this regard relate to the researcher's behavior algorithms that are acceptable in professional ethics. Due to this reason, ethical requirements must be developed not just by professional communities of genetic scientists, but also by industry medical associations (for instance, professional communities of oncologists including medical clinical genetic scientists) [10].

Moreover, it is suggested in the Russian legal literature that a qualitatively new model of genomic research self-regulation should be used. However, it's about the experimental experience [11]. Thus, we need to pay attention to basic legal regulation.

The acting Federal Law as of December 1, 2007 No. 315-FZ 'Concerning self-regulatory organizations' states that self-regulation is an independent and initiative activity implemented by the subjects of entrepreneurial or professional activity and that its content consists of development and establishing standards and rules of the mentioned activity and control over compliance with the requirements of the mentioned standards and rules. In this case, two forms of self-regulation are possible:

- self-regulated organizations that unite the subjects of entrepreneurial activity considering the unity of the sector that produces goods (works, services) or market of the produced goods (works, services);
- self-regulated organizations that unite the subjects of professional activity of a certain type [12].

Modern medicine is based on epidemiologic research results, whereas clinical practice rests on the principle of Evidence Based Medicine. The both approaches mean that probability estimates and risk estimates (results of genome deciphering require that a specialist could determine and assess the possible risk, whereas a consumer needs to perceive the risk adequately and take a willful decision) are being utilized [13]. This model of interrelations must be reflected in the legislation of the Russian Federation with subsequent specialization at the sublegislative legal level.

In this regard, in Russian legal literature it is correctly noted that the issues associated with the legal sphere must be solved within self-regulated organizations uniting the subjects of professional activity (professional associations):

- informed consent to conduction of genetic research and protection of sensitive data obtained as a result of the research;
- participation of self-regulated associations of medical genetic scientists in development of national quality standards of genetic research, requirements to medical and non-medical organizations, and employees who provide the services;
- legalizing the status of a person who provides consultations services in the sphere of genetic research and accompanying spheres associated with determining the treatment strategy of genetic diseases and use of assisted reproductive technologies (genetic consultants);
- the issues of compliance with international and national ethical requirements to conduction of the research [14: 36].

However, the noted pressing issues have not been properly regulated by the Russian legislation until now.

Thus, the issue about the balance of interests of various participants of genetic research and selection of an optimal model that legally regulates the noted social relations is still one of the major issues [15]. On the one hand, the rights, freedoms and interests of the patients and their relatives need to be followed. On the other hand, excessive restrictive regulation can significantly complicate and actually slow down development of the Russian genetic science, which can currently be inferior to the countries that lead in this sphere (USA, Great Britain, Germany, France, etc.).

CONCLUSIONS

Based on the abovementioned facts, the following conclusions can be made:

1. Nowadays Russia lacks a complex legislation regulating the status of genomic research participants, though the sphere is perspective and very important for the society and country (the fact being reflected not just in scientific literature, but also in bylaws and instruments of strategic planning). It could be associated with a complex selection of an optimal model of legal regulation that would sufficiently protect human rights and freedoms (patients, donors, relatives), promote development of science and respective sphere of provision of medical services and serve the national (public) interests.
   In this context of 'legal vacuum', the basic rule for doctors, scientific researchers and medical workers who participate in this research consists in the no-harm rule. This provision should also promote urgent and complete information of a patient of any risks of a medical intervention.
2. It is assumed that scientists and experts can determine the boundary of allowable behavior as far as genomic research is concerned by developing the respective documents. In this regard, it should be noted that apart from legislative regulation of the considered area of social relations, it is self-regulation of genetic research — regulation by organizations that conduct genetic research, their associations, and respective professional and scientific communities (by means of local acts, agreements, memoranda, professional standards, ethical codes), relations in the sphere of the organization, conduction and using the results of genetic research — which is essential in the world practice. Their analysis will enable to understand the general condition of self-regulation in this sphere and develop an optimal model of self-regulation for these organizations and subsequent legislative regulation of genetic research in the Russian Federation.
   However, the general regulative potential of bylaws of Russian companies that conduct genetic research is not currently fulfilled to a significant extent. This corresponds to general fragmentary nature of the legislative basis and compliance practice. The institution of genetic research self-regulation is poorly developed in Russia. The fact is being supported by analysis of data about activity of the corresponding companies (both state, and non-state) from the web site (primarily, on the Internet). Published ethical codes about genetic research, standards of genomic research approved by genomic organizations, documents protecting the rights of patients who participate in genetic research, etc. are nearly non-existent.
3. Insufficient legislative regulation and self-regulation of genetic research in Russia can promote violation of patients' rights and freedoms with regard to ensuring security of genetic data, protection from voluntary gene editing, transfer of the obtained genetic material to the third persons without a patient's consent, etc. Apart from that, the situation will produce a negative effect on genetics (genetic research) reputation in the society, decreased trust of citizens in this science, securing a position about a great danger of genetics relating to violation of human rights in public opinion.
4. Within the purpose of intense development of genetic technologies that has been set earlier, the country should create necessary conditions, including those of legal nature, that could promote achievement of the set tasks. Legal regulation of the status of legal research participants and ensuring security of genetic data still belong to one of these tasks. Genetic data obtained during respective genetic research must be protected from any unauthorized use, whereas rights, obligations, guarantees and legitimate interests of genetic research participants should be regulated at the level of legislation, so that they could correspond to well-known international standards and advanced foreign practices.

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