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Research Article

# Self-Regulation of genetic studies in Russia: search for the optimal model

**Emil V. Alimov*, Felix A. Leshchenkov**

The Institute of Legislation and Comparative Law under the Government of the Russian Federation,
*Moscow, Russian Federation*
* emil.alimov@gmail.com

**Abstract.** The article is devoted to the general analysis of self-regulatory practices of genetic research in Russia (conducted by public research institutions and commercial companies). Self-regulation is a special type of regulation, performed by organizations providing genetic research and their associations as well as by relevant professional and scientific community; it is regulated by local acts, agreements, memoranda, professional standards, codes of ethics, etc. and is aimed at establishing relationships in the field of organization, provision and use of results of genetic studies. Basically, self-regulation is especially critical in various aspects of organization and conducting genetic research in the worldwide perspective. The analysis provided by this article allows concluding that self-regulation practice in Russia is applied in several public research institutions, but rather fragmentarily. Moreover, the development of such form of regulation goes slowly. At the same time non-public genomic institutions are trying to evade any significant self-regulation of their activities; they do not provide for any expanded rules or standards of their practices (or they just confine themselves to references and general provisions which are not in line with the specifics of the mentioned activities). On the other hand, it is important to keep in mind that the current Russian legislation is full of gaps in terms of regulating genetic research process. Analysis of several websites of Russian private companies providing genetic profiling services revealed that those organizations almost never place complex information guides on their information portals; they neither provide the standards for performing genetic research in an intelligible form. The websites do not contain any information on possible risks or threats to health connected with application of medical procedures, while the issue of disclosure the gathered genomic information to third parties (e.g., enforcement agencies) is often ignored. More than that, there are hardly any published standards for conducting genomic research or documents on protecting patients' rights, etc. Thus, we are forced to acknowledge that the institute of self-regulation in the field of genetic studies is not developed well enough in Russia. The current fragmented nature of legal regulation and self-regulation concerning genetic research may contribute to violation of rights and legitimate interests of patients in terms of confidentiality and safeguarding genetic information, gathered in the process of research. The state therefore should within the established goals of intensive genetic technological devel-

opment provide all the necessary conditions (including of legal character). However, it is still not clear how the issues of legal regulation of status of genetic research participants, protection of genetic data, incentives for providing genetic research, etc. should be handled. We assume that one of the possible ways of tackling the aforementioned challenges is developing relevant complex legal regulation (including departmental acts) and/or investing the frontline public research institutions with special functions (i.e., within a special council, commission, or association). Such powers will contribute to regulating certain aspects of administering and conducting genetic research and using its results in the framework of legal regulation, which should be mandatory, including for non-public organizations, offering genetic services in the territory of the Russian Federation.

**Key words**: legal regulation, self-regulation, genetics, genomic policy, human genome, genetic research, personal data

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Научная статья

# Саморегулирование генетических исследований в России: поиск оптимальной модели

**Э.В. Алимов*, Ф.А. Лещенков**

Институт законодательства и сравнительного правоведения
при Правительстве Российской Федерации,
*г. Москва, Российская Федерация*
* emil.alimov@gmail.com

**Аннотация.** Статья посвящена общему анализу практики саморегулирования генетических исследований в России (как государственными научными организациями, так и коммерческими компаниями). Саморегулирование представляет собой регулирование организациями, осуществляющими генетические исследования, их объединениями, а также соответствующим профессиональным и научным сообществом (посредством локальных актов, соглашений, меморандумов, профессиональных стандартов, этических кодексов) отношений, складывающихся в области организации, проведения и использования результатов генетических исследований. В целом в мировой практике регулирования различных аспектов организации и проведения генетических исследова-

ний саморегулирование генетических исследований играет особую роль. Проведенный в статье анализ позволил сделать вывод, что в России практика саморегулирования, хотя и крайне фрагментарно, но все же применяется в ряде государственных научных учреждений. Можно отметить в целом медленное развитие такого регулирования в России в государственных научных учреждениях. При этом негосударственные геномные организации в целом уклоняются от значимого саморегулирования своей деятельности, не предусматривая каких-либо расширенных правил и стандартов о своей деятельности (либо ограничиваясь отсылочными формулировками, общими положениями, не отвечающими специфике данной деятельности). Вместе с тем важно учитывать, что действующее законодательство Российской Федерации имеет значительные пробелы в области регулирования процесса генетических исследований. Посредством проведенного в статье анализа ряда интернет-сайтов российских частных компаний, оказывающих услуги генетического профиля, авторы пришли к выводу, что данными организациями практически не проводится работа по созданию комплексных информационных пособий (на их информационных порталах), а тем более стандартов проведения генетических исследований в доступной для пациентов форме. Также в открытой форме нет сведений о возможных рисках и угрозах для пациентов в связи с применением той или иной процедуры, редко раскрывается вопрос о возможности предоставления полученной геномной информации о пациенте третьим лицам (например, правоохранительным органам). Приходится констатировать, что в России в целом недостаточной степени развит институт саморегулирования генетических исследований. Этот вывод был сделан на основе проведенного анализа информации об организации и деятельности отмеченных организаций (государственных и коммерческих), имеющейся в открытом доступе. Так, например, практически отсутствуют опубликованные стандарты проведения геномных исследований, документы о защите прав пациентов — участников генетических исследований и др. Сложившийся в настоящее время фрагментарный характер законодательного регулирования и саморегулирования генетических исследований может способствовать нарушению прав и законных интересов пациентов в части обеспечения конфиденциальности и сохранности генетической информации, полученной в ходе генетического исследования. Соответственно, государство в рамках поставленной цели интенсивного развития генетических технологий должно создать необходимые условия, в том числе правового характера, которые способствовали бы последовательному достижению поставленных задач. Однако нерешенными до настоящего времени остаются такие задачи, как: правовая регламентация статуса участников генетических исследований, защита генетической информации граждан, стимулирование проведения генетических исследований и др. Представляется, что возможным способом решения отмеченных проблем является осуществление соответствующего комплексного правового регулирования (в том числе с помощью ведомственных актов), а также рассмотрение вопроса о предоставлении ведущим государственным научным учреждениям специальной функции (например, в рамках отдельного совета, комиссии или ассоциации) по регулированию отдельных аспектов организации, проведения генетических исследований и использования их результатов (в рамках законодательного регулирования), что должно иметь обязательный характер, в том числе для негосударственных организаций, оказывающих услуги генетического характера на территории Российской Федерации.

**Ключевые слова:** правовое регулирование, саморегулирование, генетика, геномная политика, геном человека, генетические исследования, персональные данные

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## Introduction

In the modern world such issues as progressive development of protective instruments for human rights and personal data, international cooperation in the field of living organism's genomics connected with revolutionary inventions in genomic projects, colossal promotion of IT in the field of bioinformatics, genomic medicine and other sciences concerning health and genomic technologies of animal and plant selection gain relevance (Yankovskiy & Borinskaya, 2003:46–49). The accumulation and exchange of genomic data is expanding exponentially, while the genomic biomedical technologies and genomic research results are being widely applied in the socially significant spheres. At the same time this field features several legal risks of abuse and possible violations of civil, social, and public interests (Montgomery, 2018).

The state should create the necessary conditions to ensure that the genetic information gathered in the process of relevant genetic research is protected against any illegal tampering, while the legal status of genetic research participants is legitimately established and corresponds to widely recognized international standards and advanced practices of foreign states (Branum & Wolf, 2015; Isasi, Kleiderman & Knopper, 2016).

It is worth mentioning that according to the current laws, all professional self-regulative organizations are bound to protect public interests by determining basic rules for professional activities. Thus, they define criteria for registration and certification, provide special guides in the form of ethics codes, professional conduct codes and practical standards, maintain an open register of specialists, deal with complaints about actions of organization members and apply relevant disciplinary sanctions. Conventional professional associations are not authorized to develop and apply obligatory requirements.

According to some authors, efficiency and resilience of self-regulation processes in terms of genomic research are ensured at three levels: international self-regulation level, interdisciplinary self-regulation level, and the level involving solution of particular issues or matters within the specialist community (Varlen at al., 2019:11–17). At the same time, the lack of well-elaborated, comprehensive, and approved by the Russian genetic (biological) science rules and standards of conducting genetic research (including the rules for handling gained genomic information and using research results), demonstrates professional disunity of specialists (research centers) performing genomic research, which ultimately hinders development of uniform legal and ethical requirements.

The most disputed topic, being heavily criticized in science, is the acceptable conduct rules for a specialist (scientist) performing genetic research from the viewpoint of professional ethics (Nanba et al., 2020). Thereupon the ethic requirements

should be elaborated not only by professional associations of genetic specialists, but also by sectorial medical associations in general. This complex and multifaceted issue under study should involve current international experience based on the provisions of relevant international agreements, concluded between international organizations (Lévesque, Joly & Simard, 2011; Lin, Owen & Altman, 2004).

The situation which has emerged in Russia in the field of genomic studies, including the legal regulation of relevant activities, shows several tendencies, among which we should note remarkable deceleration of Russia in comparison with the leading foreign states (Mashkova, Shirokov, 2020). Thus, Section I — The Status of Genetic Technological Development in the Russian Federation of the Russian Government Regulation No 479 of April 22, 2019 On the Approval of the Federal Scientific and Technical Development Program for Genetic Research 2019–2027 — officially states that "the share of Russia in the general volume of worldwide genetic technology market is critically low. Russian achievements and studies in the field of genetic technologies will not allow reaching large amounts of commercially successful results, so the necessary products are being imported. Therefore, the share of Russian import of amino acids (tryptophan, threonine, and valine) used for agricultural animal feed reaches 100 percent, ferments — over 70 percent".

At the same time, we should note the urge of the Russian government to regulate those social relationships and stimulate genetic studies overall. However, at the moment, there is still no legal certainty in matters of legal regulation concerning nature, methods, and standards for conducting genetic and genomic research, prevention and elimination of genetic discrimination, as well as maintaining an optimal balance between privacy of personal data and possibilities of so-called *open science* (Lapaeva, 2020).

Therefore, lack of full-fledged legal regulation of genetic research in the Russian Federation attaches greater relevance to the self-regulating norms of organizations, performing genetic research in the Russian Federation. Their analysis would allow better understanding of the general stance of self-regulation in this field along with determining the vectors for achieving the optimal model of self-regulation for those organizations**.**

**Self-Regulation of genetic research in Russian public research institutions**

Among public research institutions we should mention the following ones: The Federal Public Budget Research Institution *Medical Genetic Research Facility (MGRF*), The Federal Public Budget Research Institution called *The Vavilov Institute of General Genetics of the Russian Academy of Sciences (IGG),* and The Federal Public Budget Research Institution called *The Federal Research Facility — the Institute of Cytology and Genetics of the Siberian Branch of the Russian Academy of Sciences (ICG).* Several core regulations of the mentioned organizations have been analyzed by the authors.

It should be noted that all the aforementioned organizations are federal public budget research institutions, which implies their subordination in relation to the concerned federal public authority — the Ministry of Science and Higher Education of the Russian Federation. That Ministry adopted their charters. The charters also provide for the status of the Ministry of Science and Higher Education as a founder of concerned research institutions by vesting it with the relevant powers and functions (despite the fact that some of them are directly subordinate to the Russian Academy of Sciences). Thus, the Charter of the IGG No 187 of July 6, 2018 states that the founder and the owner of all property of the Institute is the Russian Federation, while the functions and powers of the owner of the property entrusted to the Institute are performed by the Ministry of Science and Higher Education of the Russian Federation and the Federal Agency for Managing Public Property in the manner, established by the Russian legislation and in accordance with the Charter.

The Charter of the MGRF No 80 of July 6, 2018 stipulates that the institution fulfils state assignments, formed and approved by the Ministry of Science and Higher Education of the Russian Federation taking into account the RAS recommendations and, in accordance with main activities, established by the mentioned Charter. At the same time, the MGRF may not deny state assignments. In order to perform its tasks, the MGRF, on its own behalf, may acquire and implement civil rights, carry civil obligations, sue and be sued in any court and independently, in the prescribed manner, form its own structure, including departments to perform medical and genetic research (medical genetic facility).

The goals and subject of the MGRF activities include pursuing fundamental, exploratory and applied (including clinical) research aimed at gaining new knowledge in the field of medical genetics, providing first aid to individuals, and training high-skilled medical and research personnel.

The MGRF engages in the following basic activities:

— To conduct fundamental, exploratory and applied research in the following directions: examining the structure, functions and variety of human genome and other human genetic materials in normal conditions, in pathological or other negative external conditions; modelling genetic processes and inherited diseases of human beings and animals, in cell colonies and by methods of bio-informatics; examining the spread, ethology and pathogenesis of inherited diseases; developing new means and methods of diagnostics, prevention and treatment of genetic pathology; developing methods (approaches) for improving efficiency of medical genetic consulting; improving administration of medical genetic assistance to Russian citizens.

— To perform research projects, funded by research grant foundations or similar organizations including international.

— To participate in coordinating activities in the field of medical genetics, including fundamental, exploratory and applied studies.

— To participate in federal, regional, sectorial and interdisciplinary programs and projects as well as in research forecasting and expert examination of scientific research.

— To participate in medical activities, to provide specialized first aid to individuals and first aid, not included in the basic compulsory health insurance program.

— To promote scientific achievements and knowledge on inherited diseases among medical personnel and general public.

— To perform activities in the field of ionizing (generating) radiation sources for the research needs; to use and store such sources.

The MGRF may also perform other, secondary activities:

1) To provide organizational, methodical, research, expert and consulting assistance for organizations within the MGRF profile.

2) To test new diagnostic and treatment methods.

3) To test medical devices.

4) To organize and conduct telemedical consultations and additional professional training by means of MGRF telecom systems.

5) To prepare standards, protocols, algorithms, and clinical recommendations on the relevant genetic medical issues.

6) To produce diagnostic systems.

7) To collect and scavenge the waste and scrap of precious metals and silver-containing components after the use of motion picture X-ray materials.

8) To conduct activities connected with legal protection and use of intellectual activity results of the MGRF according to the Russian legislation.

9) To lease temporary unused property, including real estate.

10) To use the exclusive rights of the MGRF to the results of intellectual activities and dispose of them in accordance with the Russian legislation.

It should be noted that the MGRF in contrast to other research institutions of a similar activity profile has approved and placed in open access a number of documents on the activities of the ethics committee, use of confidential information and procedure of handling public petitions. Thus, MGRF Order No 2/16 of January 11, 2016 has established the standard operating procedures (SOP) of the local ethics committee in accordance with legislative requirements in order to perform independent expert examination, provide consultations and make decisions on the biomedical research ethics, implying human or animal participation. Apart from that on August 28, 2017 the MGRF approved the Regulation on Confidential Information in conducting clinical studies of medicinal drugs, which generally regulates the procedure for handling various confidential data types (professional secrecy, commercial secrecy, medical privacy, sensitive information constituting State secrets) in order to ensure the MGRF economic and legal security in performing clinical studies of medicinal drugs.

The IGG Charter states that the Institute conducts fundamental, exploratory and applied research and design studies in a variety of areas: general, molecular and evolutionary genetics, human, plant and microorganisms genomics, structural and functional genome organization, mechanisms for gene regulation and expression, comparative genomics, system biology, genetic security, genetic passportization and DNA identification, genetics of agricultural animals and plants, gene pools, human

genomic geography in Russia and worldwide, etc. It is also noted that the research activities of the IGG are connected with highly sensitive information.

The ICG Charter No 414 of July 26, 2018 generally provides for similar matters, mentioned above, which demonstrates a uniform approach to the composition of establishing documents of such public research institutions. We should also note the Ethics and Professional Conduct Code of the ICG workers, adopted on September 12, 2017. That Code represents a compilation of general professional ethical principles and rules of conduct, which all the ICG staff should adhere to, independently of their position. In the process of concluding a labor agreement the candidates shall study the Code provisions and follow them in the future. The main purpose of the Code is to generalize ethical standards and establish rules of professional conduct for the ICG staff to ensure their effective performance as well as strengthen the ICG authority and/or business reputation. The ICG Ethics and Professional Conduct Code is aimed at improving staff efficiency, thus the Code:

1) serves as a basis for consistent development of corporative culture and formation of strong work ethics,

2) serves as an institute of public conscience and dignity of the ICG workers as well as creates atmosphere of trust and mutual respect,

3) prevents corruption and contributes to removing reasons for corruption and conflicts of interest.

It also establishes that knowledge and commitment to the rules of ethics and professional conduct code of the ICG staff is one of the criteria for assessing their professional activities and performance.

According to the Code the staff shall:

a) perform their duties within the powers, determined by the job description, fairly and professionally, in order to secure the ICG effectiveness,

b) follow the norms of professional ethics,

c) provide assistance to colleagues in order to reach higher results and share experience,

d) manage entrusted resources effectively and handle the assigned property with care,

e) refrain from activities, which pursue private interests and hinder proper execution of professional duties,

f) inform the ICG management, the prosecutor's office and other relevant public authorities about all cases of corruption and engagement in corrupt schemes,

g) demonstrate professional independence, excluding all possible external influence, including from political parties, public associations, etc.,

h) pay attention, show respect, and follow etiquette in all professional communications,

i) refrain from behavior which may question the proper execution of professional duties, avoid conflicts which may jeopardize the ICG reputation and/or authority,

j) not receive rewards for their professional performance from individuals or legal entities (including fees, loans, services, entertainment, recreation, transport expenses reimbursement, and other rewards),

k) take all necessary measures, provided by the Russian legislation and prevent conflicts of interest and mitigation thereof,

l) comply with the established rules of public speaking and provision of professional information according to the ICG regulations and relevant legal norms of the Russian Federation.

For not compliance with the provisions of the ICG Code an employee bears moral responsibility to their employer and colleagues as well as other responsibilities in accordance with the legislation of the Russian Federation. Compliance with the ICG Ethics and Professional Conduct Code is taken into account during attestation, building a talent pool for promotion to higher positions, deciding on incentives and also when imposing disciplinary sanctions.

Moreover, the ICG has adopted the Development Program for 2016–2020 of strategic nature that provides for a well-detailed plan to achieve the established goals. Objectives of the Development Program include acquiring new fundamental knowledge in the field of general and molecular genetics, developing new genetic, cellular and bioinformation technologies to satisfy the needs of biomedicine, agriculture, and biotechnological industry of the Russian Federation.

Thus, the charters of the mentioned public research institutions contain no provisions, which would directly regulate rights, obligations, liability and guarantees of the participants of genetic research. The charters regulate the most general matters of organizational, legal and financial nature. At the same time, they provide for the main activity vectors of genetic studies as well as main responsibilities to superior federal authorities. All the mentioned research institutions have ethical committees, but only the ICG has developed the code of ethics. We can only find the most general information on such committees in the open access. Despite the fact that several famous federal public budget research institutions have been working for a long time in Russia (the MGRF, the IGG, the ICG and others) there is no publicly available information concerning their cooperation (excluding joint research projects and participation in scientific events) in the field of development and adoption of ethically oriented documents of genomic research, strategic instruments, etc.

All the public research institutions, examined above, should in the course of their activities undertake public assignments as they are funded from the Russian federal state budget; they should also conduct works, which may be connected with national security secrecy. Therefore, the activities of the relevant research institutions are closely connected with and are greatly directed at implementing state policy in the field of biomedical research, including genetic studies. Only the ICG has adopted and placed their development program 2016–2020 on the official website. Other mentioned institutions still have such opportunity; moreover, they may have developed and adopted similar programs but, apparently, they have limited access status, since they can be associated with professional secrecy and national security.

**Self-Regulation of genetic research in Russian non-public organizations**

The mapping of the human genome provides for new wide prospects of using the gathered information in medicine. Commercial medical facilities are increasingly offering services of genetic research and personal genomic testing in recent years (Mashkova, Varlen & Shirokov, 2020:56). The constant drop of prices on such services attracts more customers interested in using test results for a wide scope of purposes. It is evident that genetic research and personal genomic testing, provided by commercial medical companies gain more popularity (Munnich, 2019:409–410; Knoppers, 2014).

The results of genetic studies may generally be used for the following purposes: for revealing disease-disposing genes, conducting relevant risk assessment, forecasting future treatment or preventive care. They are also critical in family planning and application of reproductive health technologies, complex risk assessment in voluntary personal insurance schemes or employment risk assessment as well as in further research.

Such services are also becoming more affordable for general public. At the same time, they allow accumulating a vast mass of genetic data at private institutions, which jeopardizes information safety and crates a menace for information leakage (Rothstein, Knoppers & Harrell, 2016). All those pose questions concerning the legal regime of such information, the degrees of self-regulation and state interference in the processes of providing medical services in the field of genetics in order to secure the rights and legitimate interests of citizens (Thorogood, Dalpé & Knoppers, 2019).

In this context it is worth mentioning the endeavor of S.S. Zenin to formulate three basic principles of building a model of optimal balance between state regulation and self-regulation of relationships in the field of performing genetic studies: the informed consent to undergo genetic testing, participation of self-regulatory associations of medical genetics in the development of the national standards on the quality of medical services, legal status of a genetic consultant (Zenin, 2020:8). Supposedly it is not about principles (basic onset and formulation), but about certain rules of conduct, rather significant in their essence, though not covering all the aspects of social relationships under consideration. Other issues also demand consideration; among them are the role of genetic (not only medical) organizations in developing and applying self-regulation, admissibility, and procedure for sharing genomic information with the third parties including enforcement agencies, matters of legal status of patients, genetic material donors, and their genetic relatives, etc.

It is worth noting that in current situation a patient should actively participate in monitoring their own health and selecting an optimal treatment scheme by using the latest genetic science achievements (Nazarov & Sisigina, 2018). At the same time, they should make well-elaborated decisions concerning gene therapy and/or genetic testing and realize their personal responsibility for decisions made. This should apparently be supplemented with necessary medical consultations (by scientists or researchers) and patient's ability to gather all the relevant information from open

sources. In this case the patient's informed consent to medical procedures and genomic research will signal a desired result (Blassime et al., 2017).

In Russia, several private companies (usually limited liability companies — LLC) are performing genetic research (specifically genomic testing). Those companies claim on their official websites that genetic tests allow mapping human genome, learning about ancestors, getting advice on sports activities, acquiring recommendations on losing weight or nutrition as well as alerting susceptibility to certain diseases. At the same time there is no legal regulation or self-regulation upon handling of such information, i.e., ethical codes or other instruments including open-access constitutional documents. This testifies to the great amount of discretion in the issues of administering genetic studies in general and little publicity in the activities of the mentioned companies in terms of self-regulation and development of ethical standards for conducting genetic research.

Moreover, most often the ethical committees/commissions are non-existent, and nothing is mentioned about adherence to any developed ethical standards of international or European levels. Yet, this situation threats genetic information safety and may violate human rights by arbitrary editing human genome or leaking information to third parties without due consent.

However, there are some exceptions. For example, Genotek provides for a confidentiality policy in handling personal data[1]. This company (established in 2010) is one of the first to perform genetic testing in Russia; it offers undergoing one of five thematic tests: Health and Longevity, Child Planning, Diet and Fitness, Talents and Sports, Genealogy. The main areas of its activities are similar to other private organizations, that provide similar services; they include:

— genetic studies for research institutions,
— DNA testing on the origin of a person (genetic genealogy),
— DNA testing for inherited diseases,
— DNA testing, revealing susceptibility to various diseases,
— pregnancy planning genetic studies,
— genetic research of human predispositions (sports, metabolism, etc.).

Atlas biomedical holding offers testing on health, nutrition, sports, origin, and personal traits. Atlas is currently one of the most popular companies in Russia, conducting genetic tests. It is worth mentioning that Atlas is famous for providing precise rules of disclosing genomic information in its confidentiality policy, which is not very typical for most companies. Those rules include:

1) inadmissible use of personal raw data of patients for research or commercial purposes without prior and clear consent (raw personal data is the type of information about genetic data of a specific person),

[1] Genotek. Available from: https://www.genotek.ru/f/Privacy_Policy_and_Processing_of_Personal_Information.pdf [Accessed 11th September 2020].

2) In the absence of a statutory obligation to disclose or transmit such information, a guarantee of non-disclosure of personal data or individual raw data of a patient to third parties is presumed[2].

MyGenetics also offers DNA testing for providing recommendations over diet and fitness[3]. The company operations in the Technopark of the Novosibirsk Academgorodok. Diagnostic results are based on the data of the National Center of Biotechnology Information (USA), the European Research Consortium Food4Me, Stanford University and other global laboratories. DNA studies are performed at the Institute of Chemical Biology and Fundamental Medicine of the Siberian Branch of the Russian Academy of Sciences. MyGenetics also provides for a confidentiality policy of general nature.

We should also mention ZAO Genoanalitika, which is located in the Science Park of the Lomonosov Moscow State University and has acquired the status of the center for collective usage in the Skolkovo Technopark[4]. The company performs genetic testing as one of three research packages: monogenic diseases, two studies and a Complete Genetic Passport" of five studies, or for each of the areas separately. The main activity areas are the following:

a) complex solutions in the field of genomic studies of any level of complexity for medical, research and agricultural purposes,

b) specialized sequencing of all types of nucleic acids,

c) genotyping and karyotyping on micromatrix,

d) fast and highly accurate bioinformatics analysis of gathered data.

The Genoanalitika website also states that this company was the first in Russia to develop mass genetic services, perinatal screening DOT-test, personal genetic research My Gene, and a modern system of genomic assessment of breeding value in animals.

We should also note the activities of the Association of Medical Genetics (AMG), which is a professional association of medical geneticists and laboratory geneticists. AMG was created in order to represent and protect professional interests of medical-genetic community by consolidating, strengthening, and developing professional ties and humanitarian contacts between specialists engaged in medical genetics. Other purposes include coordinating professional activities of medical geneticists and laboratory geneticists as well as promoting medical education and continuous medical training of specialists[5]. AMG contributes to introduction of advanced experience and recent developments of world science and technologies into practical public health care,

[2] Atlas. Available from: https://atlas.ru/privacy [Accessed 24th September 2020].

[3] National Center for genetic Research MyGenetics. Available from: https://mygenetics.ru [Accessed 24th September 2020].

[4] Genoanalitika. Available from: https://genoanalytica.ru [Accessed 24th September 2020].

[5] Charter of AMG. Available from: http://amg-genetics.ru/assets/components/themebootstrap/docs/%D0%A3%D0%A1%D0%A2%D0%90%D0%92%20%D0%90%D0%9C%D0%93.PDF [Accessed 15th October 2020].

as well as promotes advanced diagnostic methods and treatment of inherited (orphan) diseases in Russia. AMG also disseminates relevant knowledge in the field of medical genetics among medical community and participates in organizing and holding scientific congresses, conferences, symposia, seminars, schools, and exhibitions. Over 300 specialists of the Russian medical genetic service are full members of the AMG including the main freelance specialists of the Russian Ministry of Health on medical genetics in federal districts and health departments of the Russian Federation constituent entities[6]. Since 2016, AMG has been implementing a joint project with the Federal State Budgetary Scientific Institution *Research Center for Medical Genetics* to create a unique database of patients with congenital and hereditary orphan diseases (Audit of Diagnostics and Medical Care for patients with inherited orphan diseases)[7]. The project has significant research perspectives and allows generalizing and studying the available data on the prevalence, diagnostic methods, and efficient treatment of severe hereditary (orphan) diseases, including phenyl ketonuria, mitral valve disease, acid maltase deficiency, Niemann-Pick C1 disease, diffuse angiokeratoma in the Russian regions. AMG is a member of the National Medical Chamber and participates in the preparation and discussion of draft laws in the field of public health care and draft clinical guidelines on hereditary (orphan) diseases in children and adults.

It seems that organization and activities of the AMG largely correspond to the best practices of relevant foreign organizations (Mashkova, Varlen & Shirokov, 2020).

## Conclusion

Currently, the Russian legislation and judicial practice do not directly provide the scope of human rights in the field of genomic studies and special legal guarantees are not enshrined. We can agree that in contrast to practice of the European Court for Human Rights, the relevant Russian judicial practice in the field of genomic studies and implementation of their results is a rather "boring landscape" of monotonous cases, generally encompassing matters of genetic identification in criminal and family procedures (Kalinichenko & Kosilkin, 2019:116).

The cornerstone issue is establishing measures of responsibility for breaking laws (by illegal actions or inaction) in the sphere under consideration. At the same time, it is obvious that harm to the patient's health in the process of conducting a genetic research in the event of negligence of a physician or scientist or medical personnel should imply their liability (Blinov, 2018). However, we should also take into account the complexity of genetic research and the situation itself in every specific case.

[6] AMG. Available from: https://med-gen.ru/spetcialistam/assotciatciia-meditcinskikh-genetikov/https://genoanalytica.ru [Accessed 15th October 2020].

[7] AMG. Available from: https://med-gen.ru/spetcialistam/assotciatciia-meditcinskikh-genetikov/https://genoanalytica.ru [Accessed 15th October 2020].

No less urgent is the task of protecting information, gained in the course of genetic research. According to the current legal regulation, application of liability measures in this area is extremely problematic, as there are no specific rules restricting human genome editing, transmission of genomic data to third parties and so on. For example, administrative law only provides liability for violating rules in the field of GMO and GMO-products.

It seems that the main rule for doctors, scientific researchers and medical personnel, engaged in genetic research, should be *do no harm to the patient, observe their rights and legitimate interests*. This rule should be facilitated by informing the patient about all possible risks of medical intervention (including genetic research).

It is also important to establish the ethical boundaries of permissible behavior in the scientific expert community by developing the relevant documents through open scientific discussion. In this context it is worth mentioning that the regulatory potential of the acts of the Russian genetic research organizations is not yet fully realized, which fragmentizes legislative framework and law enforcement practice. At the same time in Russia as a whole, the institute of self-regulation in genetic research is poorly developed, which is confirmed by the analysis on the information concerning the activities of relevant organizations (private and public) available in the public domain (primarily, the internet).

At the same time, the insufficient (fragmented) legal regulation and self-regulation of genetic studies lead to violations of patient's rights and legitimate interests in terms of information confidentiality and genetic data security. Moreover, such situation may negatively affect the reputation of genetic research in society.

The state therefore should within the framework of the set goals of intensive genetic technological development create all the necessary conditions (including of legal nature). At the same time reaching such a global aim is impossible without due legal regulation of the status of genetic research participants, and without securing genetic information about citizens. The state should ensure that the genetic information gathered from the relevant genetic research is protected against any illegal tampering, while the rights, obligations, guarantees and legitimate interests of genetic research participants are fairly established in order to comply with generally recognized international standards and best practices of foreign states.

Summing up, we should note that in Russia the practice of self-regulation is being applied, though rather fragmentally, in many research institutions. We may notice the constant, yet slow, development of such regulation in Russian public research institutions. At the same time private genomic organizations generally evade significant regulation of their activities and thus do not provide for the rules or standards of their activities, limiting themselves to referential formulations, general provisions, which are not sufficient for the specifics of those activities. In this case we have to admit that private genomic organizations (operating on a commercial basis) only follow the norms of the Russian current legislation, which, as noted earlier, has significant gaps when it comes to regulation of genetic research procedures.

Analysis of several websites of Russian private companies, providing genetic profiling services[8] allows to conclude that these organizations do not work on developing complex information guides (on their information portals) and standards of conducting genetic research in the intelligible format. Moreover, the open sources provide no information on the possible risks and threats to patients in connection with application of certain medical procedures, while the issue of patient's genomic information transmission to third parties (e.g., enforcement agencies) is rarely commented on.

We assume that one of the possible ways of solving the aforementioned issues is the development of the relevant legal regulation (including departmental acts[9]) and/or organization of special activities by the leading public research institutions (i.e., in the format of a separate council, commission or association[10]) on regulating various aspects of genetic research, which will be mandatory also for non-governmental organizations, providing relevant services in the Russian territory.

## References / Библиографический список

Alimov, E.V. (2020) The Legal Status of Participants in Genetic Research in Russia: Statement of the Problem. *Vestnik of Moscow City University. Series "Legal Sciences"*. (3), 33–41. Doi: 10.25688/2076-9113.2020.39.3.04 (in Russian).

*Алимов Э.В.* Правовой статус участников генетических исследований в России: постановка проблемы // Вестник МГПУ. Серия «Юридические науки». 2020. № 3. С. 33–41. Doi: 10.25688/2076-9113.2020.39.3.04

Blasimme, A., Moret, C., Hurst, S.A. & Vayena, E. (2017) Informed Consent and the Disclosure of Clinical Results to Research Participants. *The American Journal of Bioethics.* 17(7), 58–60. Doi: 10.1080/15265161.2017.1328532

Blinov, A.G. (2018) Legal Environment of Genome Research and Prospects of its Optimization in Russia. *Herald of Omsk University. Series "Law"*. 4(57), 138–144. Doi: 10.25513/1990-5173.2018.4.138-144 (in Russian).

*Блинов А.Г.* Правовая среда проведения геномных исследований и перспективы ее оптимизации в России // Вестник Омского университета. Серия «Право». 2018. № 4(57). С. 138–144. Doi: 10.25513/1990-5173.2018.4.138-144

Branum, R., Wolf, S. M. (2015) International Policies on Sharing Genomic Research Results with Relatives: Approaches to Balancing Privacy with Access. *The Journal of Law, Medicine & Ethics.* 43(3), 576–593. Doi: 10.1111/jlme.12301

[8] Atlas. Available from: https://atlas.ru; Genotek. Available from: https:// https://www.genotek.ru; Genetico. Available from: https://genetico.ru; Evogen. Available from: https://evogenlab.ru; Center for Molecular Genetics. Available from: http://www.dnalab.ru; Medical Center Kind Doctor. Available from: https://doctor-rzn.ru; National Center for Genetic Research MyGenetics. Available from: https://mygenetics.ru; Genoanalitika. Available from: https://genoanalytica.ru [Accessed 24th September 2020].

[9] Thus we can note various professional standards (in particular of the Russian Ministry of Labor): the Professional standard of the genetic medical specialist; the Professional standard of the KDL physician; the Professional standard of the clinical cytology specialist; the Professional standard of a bio-chemical physician (see: Professional standards. Available from: http://amg-genetics.ru/normativnyie-dokumentyi/profstandartyi [Accessed 22th November 2020].

[10] It is possible to perform such complex activities on the basis of the AMG.

Dubov, A.B. & Dyakov, V.G. (2019) Genomic Information Security: Legal Aspects of International and National Regulation. *Courier of the Kutafin Moscow State Law University (MSAL)*. (4), 127–137. Doi: 10.17803/2311-5998.2019.56.4.127-137 (in Russian).
*Дубов А.Б., Дьяков В.Г.* Безопасность геномной информации: правовые аспекты международного и национального регулирования // Вестник Университета имени О.Е. Кутафина (МГЮА). 2019. № 4. С. 127–137. Doi: 10.17803/2311-5998.2019.56.4.127-137

Isasi, R., Kleiderman, E. & Knopper, B.M. (2016) Editing policy to fit the genome? *Science*. 351(6271), 337–339. Doi: 10.1126/science.aad6778

Kalinichenko, P.A. & Kosilkin, S.V. (2019) Genomic Research: Council of Europe Standards and Legal Regulation in Russia. *Courier of Kutafin Moscow State Law University (MSAL)*. (4), 108–118. Doi: 10.17803/2311-5998.2019.56.4.108-118 (in Russian).
*Калиниченко П.А., Косилкин С.В.* Геномные исследования: стандарты Совета Европы и правовое регулирование в России // Вестник Университета имени О.Е. Кутафина (МГЮА). 2019. № 4. С. 108–118. Doi: 10.17803/2311-5998.2019.56.4.108-118

Knoppers, B.M. (2014) International ethics harmonization and the global alliance for genomics and health. *Genome Medicine*. 6(2), 13. Doi: 10.1186/gm530

Lapaeva, V.V. (2020) Concept of Improving Russian Legislation Regulating the Development of Research in the Field of the Human Genome. *Proceedings of the Institute of State and Law of the RAS*. 15(2), 111–134. Doi: 10.35427/2073-4522-2020-15-2-lapaeva (in Russian).
*Лапаева В.В.* Концепция совершенствования российского законодательства, регулирующего развитие исследований в области генома человека // Труды Института государства и права РАН. 2020. Т. 15. № 2. С. 111–134. Doi: 10.35427/2073-4522-2020-15-2-lapaeva

Lévesque, E., Joly, Y. & Simard, J. (2011) Return of Research Results: General Principles and International Perspectives. *Journal of Law, Medicine & Ethics*. 39(4), 583–592. Doi: 10.1111/j.1748-720X.2011.00625.x

Lin, Z., Owen, A.B. & Altman, R.B. (2004) Genomic Research and Human Subject Privacy. *Science*. 305(5681). Doi: 10.1126/science.1095019

Mashkova, K.V. & Shirokov, A.Yu. (2020) The Formation of the Legal Status of Applied Genomic Research through the Formation of Self-Regulatory Professional Associations. *Actual Problems of Russian Law*. 15(10), 132–140. Doi: 10.17803/1994-1471.2020.119.10.132-140 (in Russian).
*Машкова К.В., Широков А.Ю.* Становление правового статуса прикладных геномных исследований через формирование саморегулируемых профессиональных ассоциаций // Актуальные проблемы российского права. 2020. № 15(10). С. 132–140. Doi: 10.17803/1994-1471.2020.119.10.132-140

Mashkova, K.V., Varlen, M.V. & Shirokov, A.Yu. (2020) Self-Regulation of Genomic Studies and Prospects of Personified Medicine. Lex Russica. (8), 54–61. Doi: 10.17803/1729-5920.2020.165.8.054-061 (in Russian)
*Машкова К.В., Варлен М.В., Широков А.Ю.* Саморегулирование геномных исследований и перспективы персонифицированной медицины // Lex russica (Русский закон). 2020. № 8. С. 54–61. Doi: 10.17803/1729-5920.2020.165.8.054-061

Montgomery, J. (2018) Modification of the Human Genome: Human Rights Challenges Raised by Scientific and Technical Developments. *European Court of Human Rights Precedents*. 3(51), 42–56. (in Russian).
*Монтгомери Дж.* Модификация генома человека: вызовы со стороны сферы прав человека, обусловленные научно-техническими достижениями // Прецеденты Европейского суда по правам человека. 2018. № 3(51). С. 42–56.

Munnich, A. (2019) La Médecine Génomique Personnalisée: Prédire ou Médire? *Bulletin de l'Academie Nationale de Medecine.* 203(6), 409–412. Doi.org/10.1016/j.banm.2019.06.006 (in French).

Nanba, S.B., Akopyan, O.A., Alimov, E.V., Garmaeva, M.A. & Bedoeva, Z.N. (2020) State Programs for the Development of Genetic Technologies. *Opción.* (26), 732–750.

Nazarov, V. & Sisigina, N. (2018) Genetic Health Economy. *Ekonomicheskaya Politika*. 13(6), 188–213. Doi: 10.18288/1994-5124-2018-6-188-213 (in Russian).
*Назаров В., Сисигина Н.* Экономика генетического здравоохранения // Экономическая политика. 2018. Т. 13. № 6. С. 188–213. DOI: 10.18288/1994-5124-2018-6-188-213

Rothstein, M.A., Knoppers, B.M. & Harrell, H.L. (2016) Comparative Approaches to Biobanks and Privacy. *The Journal of Law, Medicine & Ethics*. 44(1), 161–172. Doi: 10.1177/1073110516644207

Thorogood, A., Dalpé, G. & Knoppers, B. (2019) Return of Individual Genomic Research Results: are Laws and Policies Keeping Step? *European Journal of Human Genetics*. (27), 535–546. Doi: 10.1038/s41431-018-0311-3

Varlen, M.V., Mashkova, K.V., Zenin, S.S., Bartsits, H.L. & Suvorov, G.N. (2019) Search for General Principles of Genomic Self-regulation Researching the Context of Ensuring Priority Protection of Rights and Legitimate Interests of the Individual. *Issues of Law*. 3(72), 11–20. (in Russian).
*Варлен М.В., Машкова К.В., Зенин С.С., Барциц А.Л., Суворов Г.Н.* Поиск общих принципов саморегулирования геномных исследований в контексте обеспечения приоритетной защиты прав и законных интересов личности // Проблемы права. 2019. № 3(72). С. 11–20.

Yankovskiy, N.K. & Borinskaya, S.A. (2003) Genom cheloveka: nauchnyye i prakticheskiye dostizheniya i perspektivy. *Analiticheskiy obzor. Vestnik RFFI*. (2), 46–63. (in Russian).
*Янковский Н.К., Боринская С.А.* Геном человека: научные и практические достижения и перспективы // Аналитический обзор. Вестник РФФИ. 2003. № 2. С. 46–63.

Zenin, S.S. (2020) State regulation and self-regulation of relations in the field of genetic research: towards the formation of an optimal moth. *Issues of Law*. 3(77), 7–8. (in Russian).
*Зенин С.С.* Государственное регулирование и саморегулирование отношений в сфере генетических исследований: к формированию оптимальной моли // Проблемы права. 2020. № 3(77). С. 7–8.

**About the authors:**

***Emil V. Alimov*** — Candidate of Legal Sciences, Researcher of Department of Constitutional Law of the Institute of Legislation and Comparative Law under the Government of the Russian Federation; 34 B. Cheremushkinskaya str., Moscow, 117218, Russian Federation

**ORCID ID: 0000-0002-0743-4210**

*e-mail:* emil.alimov@gmail.com

***Felix A. Leshchenkov*** — Researcher of the Department of Constitutional, Administrative and Criminal Law and International Law of the Institute of Legislation and Comparative Law under the Government of the Russian Federation; 34 B. Cheremushkinskaya str., Moscow, 117218, Russian Federation

**ORCID ID: 0000-0003-2221-6710**

*e-mail:* foreign2@izak.ru

**Об авторах:**

***Алимов Эмиль Ваизович*** — кандидат юридических наук, научный сотрудник отдела конституционного права, Институт законодательства и сравнительного правоведения при Правительстве Российской Федерации; 117218, Российская Федерация, г. Москва, ул. Большая Черемушкинская, д. 34

**ORCID ID: 0000-0002-0743-4210**

*e-mail:* emil.alimov@gmail.com

***Лещенков Феликс Артемович*** — научный сотрудник отдела конституционного, административного и уголовного законодательства и международного права, Институт законодательства и сравнительного правоведения при Правительстве Российской Федерации; 117218, Российская Федерация, г. Москва, ул. Большая Черемушкинская, д. 34

**ORCID ID: 0000-0003-2221-6710**

*e-mail:* foreign2@izak.ru