

# Contemporary Challenges and Legal Regulation of Genome Research: Some Considerations

Alexey V. Kubyshkin

*Scientific Collaboration “Legal Genomics Developments Alliance (LeGenDA)”, Moscow, Russia*

**Abstract:** The paper studies some aspects and considerations of the legal regulation of genomic research in the context of modern challenges. Approaches to the formulation of some basic concepts in the field of bioinformatics, such as information, information space, are proposed, the importance of these concepts for legal regulation is substantiated. Approaches to the legal regulation of the commercial use of the results of genomic research in the field of bioinformatics are formulated. Approaches to the legal regulation of the activities of biobanks are proposed based on the analysis of the possibility of using blockchain technology to improve the functioning of the biobank, the possibility of attracting investments through crowdfunding financing. The classification of biobanks according to various criteria is given. Approaches to the formulation of such concepts as donation and parenthood are determined within the framework of the legal regulation of genomic research in the field of human reproduction. The influence of modern challenges associated with the development of science and technology on the formulation of these concepts is considered. Approaches to solving the problem of ensuring a balance of private, group and general interests in the field of legal regulation of genomic research are proposed.

**Keywords:** Legal regulation, genomic research, bioinformatics, biobanks, blockchain, crowdfunding, donation, parenthood, balance of interests, information society, economic models, commercial use, human reproduction, comparative legal research

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## Contents

I. Introduction . . . . .	37
II. Bioinformatics: Basic Concepts and Approaches to the Commercial Use of Research Results . . . . .	38
III. Biobanks Activities Issues . . . . .	45
IV. Modern Challenges and Definition of Concepts in the Sphere of Legal Regulation of Genomic Research . . . . .	54
V. Ensuring a Balance of Interests as the Basis for Legal Regulation of Social Relations in the field of Genomic Research . . . . .	59
VI. Conclusion . . . . .	61
References . . . . .	63

## I. Introduction

Within the framework of this paper, we would like to dwell on some aspects and considerations of the legal regulation of genomic research in the field of reproduction, biobanking and bioinformatics, which arose in connection with the emergence of new factors that significantly affect social relations, including those in such a sensitive area as genomic research.

In our opinion, one of the defining factors affecting social relations is the transition to an information society from an industrial society.

An information society is a society in which information and the level of its application and accessibility radically affect the economic and socio-cultural living conditions of citizens.

The information society is opposed to the industrial society, which was formed in the process and as a result of industrialization, the development of machine production, the emergence of adequate forms

of labor organization, the application of the achievements of technical and technological progress (Rayzberg, Lozovskiy and Starodubtseva, 2011).

According to the American sociologist D. Bell, the information society is a post-industrial society characterized by the transition from the production of things to the production of services, changes in the employment of the population and the central role of theoretical knowledge (Bell, 1999).

## **II. Bioinformatics: Basic Concepts and Approaches to the Commercial Use of Research Results**

The rapid development of information technology has led to the emergence of new branches of knowledge and science, new areas of activity, areas of application of new technologies. With regard to the field of genomic research, we can talk about the emergence of such a branch of knowledge as bioinformatics.

Bioinformatics is a relatively new and rapidly developing discipline. As rightly noted by D.V. Ponomareva, genetic information and the way we use it are already changing our world, our views on human history and our approach to health matters (Ponomareva, 2020). All this makes bioinformatics an increasingly topical field of knowledge that requires legal research in order to form a regulatory environment.

Approaches to formulating the very concept of bioinformatics are quite different. So, for example, in the Russian Federation the definition of bioinformatics in one of the regulatory legal acts is formulated as follows: Bioinformatics (syn. — “Computational Biology”) is a biological discipline engaged in the research, development and application of computational methods (including computer) and approaches to expand the use of biological, behavioral or health data.<sup>1</sup>

Foreign researchers, for example, give the following definitions of bioinformatics:

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<sup>1</sup> “VP-P8-2322. Comprehensive program for the development of biotechnology in the Russian Federation for the period up to 2020” (approved by the Government of the Russian Federation dated 24.04.2012 No 1853p-P8).

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The field of bioinformatics includes the storage, retrieval, and interpretation of various types of biological data, including nucleotide and amino acid sequences, protein domains, and protein structures. One of the main tasks of bioinformatics is the study and development of tools that provide effective access to and management of various biological data (Hamdi-Cherif, 2010).

Bioinformatics is the use of computers to handle, and interpret, biological information (McCubbin, 2003).

Bioinformatics: an umbrella term linking biological data with techniques for information storage, access, and analysis to support multiple areas of scientific research and clinical treatment (Capps et al., 2019).

As we can see, the definitions are very different. The main characteristic of bioinformatics, which is reflected at almost all definitions or concepts, is the connection between biological data and information, the processing of biological data using computer information technologies.

For the purpose of formulating approaches to the legal regulation of this sphere of social relations, in our opinion, it would be advisable to consider in more detail the concept of information and information space, which is even more relevant, given the development of an informational, post-industrial society.

The concept of information first became an object of deep scientific research with the advent of cybernetics. The founder of this science N. Wiener determined that information is not energy or matter, but a designation of the content received from the external world in the process of adaptation to it (Wiener, 1958). As you can see, the specified definition of information reflects two important features of this concept, which are recognized by most researchers of information as a phenomenon. First, it is established that the information is intangible. It is this feature that determines the specifics of the legal regulation of information relations. Secondly, N. Wiener's definition indicates that information is a certain content, that is, information, facts obtained from the external world in the process of adaptation, and, consequently, in the process of interaction with the external world.

A similar definition can be found in the dictionary of S.I. Ozhegov (1990). In accordance with this definition, information is 1) data about the surrounding world and the processes occurring in them, perceived by a person or a special device, 2) generalizations, informing about the state of affairs, about the state of something (Ozhegov, 1990).

Considering information from a socio-economic point of view, a number of domestic scientists have formulated the following definition: information is a set of data about nature and society, the processes that occur there and are reflected in the consciousness of people (Plakhotnoy, 1992).

In some cases, information is understood not as specific data, facts, but as a process of transmission of messages, data. For example, in the Soviet encyclopedic dictionary, information is the exchange of data between people, a person and an automaton, an automaton and an automaton, the exchange of signals in the plant and animal world, the transmission of signs from organism to organism (Soviet Encyclopedic Dictionary, 1989, p. 504).

According to Ermishina (1988), information is the transmission of news, messages about events, as well as scientific and technical information, videotapes and records, various types of printed information, etc. There is distinction between the concept of “information” as a means, process and “information” as a result. As you can see, in this definition she attempts to combine two main features in the concept of information: first, to present information as data, facts, and secondly, to consider information as a process of data transferring.

According to the Dictionary of Foreign Words, the concept of information includes: 1) a message about something, 2) information that is an object of storage, processing and transmission, 3) in mathematics, cybernetics — a quantitative measure of eliminating uncertainty (entropy), a measure of system organization (Modern Dictionary of Foreign Words. 1993, p. 254).

According to UNESCO, information is a universal substance that permeates all spheres of human activity, serving as a conductor of knowledge and opinions, an instrument of communication, mutual understanding and cooperation, and the approval of stereotypes of thinking and behavior (Lopatin, 2000).

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A very important feature of information, which, on the one hand, determines the complexity of the legal regulation of social relations concerning information, the difficulty of establishing a legal regime, and on the other hand, determines the simplicity and ease of occurrence, change and termination of these relations, is the intangible nature of information. Nevertheless, information, being intangible in essence, cannot be considered without a tangible carrier, while it is necessary to distinguish between relations regarding information, information carrier and information located on the information carrier. This feature, which characterizes information as a combination of intangible content and material carrier, is of great importance for understanding the essence of the information space, approaches to legal regulation of which will be discussed later.

Thus, based on the generalization of the main features of information, the following definition of the concept of “information” can be proposed: Information is an intangible object that is data, facts, as well as the results of their assessment in the mind of a person, mediating interactions and connections within the framework of human society, systems subject-object, subject-subject, object-object, as well as a set of genetic characteristics of the organism. Information is also a process of transferring information, messages, facts, signs from organism to organism in living nature.

The development of information technology has led to the widespread penetration of the Internet both in everyday life and in scientific life. All this allows us to speak about the formation of the information space as a special sphere of social relations in connection with information, including directly related to bioinformatics.

Various definitions of information space or information environment are now known. For example, according to the UN Secretary General’s Report, the information space is understood as the sphere of activity related to the creation, transformation and use of information, including individual and social consciousness, information and telecommunication infrastructure and own information.<sup>2</sup>

Within the framework of the CIS, the following definition of the information space was developed: information space — a set of

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<sup>2</sup> UN document A/55/140, p. 3.

databases and data banks, information and telecommunication networks and systems, as well as technologies for their maintenance and use, functioning on the basis of general principles and according to the rules that ensure information interaction between organizations and citizens, and also meeting their information needs.<sup>3</sup>

In the Decree of the President of the Russian Federation dated 09.05.2017 No 203 “On the Strategy for the Development of the Information Society in the Russian Federation for 2017–2030”, the information space is defined as a set of information resources created by subjects of the information sphere, interaction facilities of such subjects, their information systems and the necessary information infrastructure.<sup>4</sup>

Thus, the information space includes two components: the information itself and the information infrastructure. It seems that when defining an information space, we should proceed basing on the presence of two aspects in information relations. Consequently, the information space can be defined as a sphere of activity that includes information itself, relations regarding the production, collection, search, processing, storage and distribution of information, as well as information infrastructure, including computers and information and telecommunication networks.

The definition of the information space in relation to the legal regulation of relations in the field of bioinformatics is important due to the fact that these relations are largely global in nature, databases are interconnected using information technologies, access to databases under certain conditions can be obtained from anywhere by using the Internet, the software is also distributed using the Internet, etc.

As shown above, information itself is intangible, but at the same time, it cannot exist without a material carrier, which characterizes the substantial dualism of information. Accordingly, in any relationship with regard to information, including in the field of bioinformatics, it is necessary to distinguish between two main aspects: relations associated

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<sup>3</sup> Decision of the CIS Economic Council “On the Concept of Scientific and Information Support of Programs and Projects of the CIS Member States in the Innovation Sphere” (Adopted in Moscow on 13.03.2009).

<sup>4</sup> Collection of Legislation of the Russian Federation, 2017, No 20, Art. 2901.

with information as an intangible substance, and relations associated with a material component (material carriers in a broad sense, objects of information infrastructure etc.).

Based on this, the approach to legal regulation can be different. Since relations regarding the material component are associated with the location and/or placing of relevant objects in certain territories that are related to a particular state and in which the state has sovereignty and, accordingly, the authority to establish legal regimes, in this part, harmonization of legislation and legal regulation in different states is possible. If we talk about the intangible component, then in this area, in our opinion, it is precisely international legal regulation or at least regulation at the level of regional integration formations is necessary, since the exchange of information may not be related to the state borders and sovereignty of any particular state.

Thus, we believe that the legal regulation of social relations in the field of bioinformatics should take into account the substantial dualism of information and, in this regard, may be a combination of international legal regulation and (or regulation at the level of regional integration entities) and harmonization of legislation and legal regulation of various states.

Within the framework of this article, we would also like to dwell on the formation of approaches to the legal regulation of the commercial use of the results of genomic research in the field of bioinformatics.

For this purpose, it seems necessary to outline the areas in which the commercial use of such results is possible.

According to some authors, Commercial value is realized in bioinformatics through the exploitation (often by way of license arrangements) of intellectual property rights in the biological molecules, databases and software (McCubbin, 2003).

Other researchers (Brown et al., 1999; Hamdi-Cherif, 2010; *Imagined Futures: Capturing the Benefits of Genome Sequencing for Society*, n.d.) point to more commercial uses in bioinformatics. These include, for example, biological modeling, gene sequence analysis, digital storage services for biological information, biological engineering, information selection and retrieval, participation in drug development, personalized medicine, and many other areas.



As for the legal regulation of the commercial use of the results of genomic research in the field of bioinformatics, it should be noted that there is currently no comprehensive regulation in this area. There is also no common approach, principles on the basis of which the consolidation, harmonization and development of legal regulation in this area would take place.

The lack of such a comprehensive legal regulation is quite understandable, since the results of bioinformatics research are manifested in various areas that were previously regulated. For example, legal status and protection of rights to computer programs and databases, copyrights, rights to inventions, industrial models, utility designs, protection of intellectual property. The same can be said about the regulation of relations in the field of information protection.

Nevertheless, the specifics of the field of genomic research leaves a serious imprint on the seemingly long-established relations and their legal regulation. That is why, in our opinion, it is necessary in this area to formulate general approaches and principles to legal regulation, based on which it would be possible to harmonize and consolidate legal regulation of the commercial use of the results of genomic research.

At the same time, in order to form effective legal regulation, in our opinion, it is necessary to smooth out the contradictions between the main points of collision of different interests in the field of genomic research, such as:

- correlation of the principle of freedom of scientific research with the need to ensure stability and security;
- correlation of various human rights among themselves;
- balance between the need to support development, progress and human rights;
- the relationship between the economic interests of large corporations and the rights of a particular person or groups of people (Astrelina, Kubyshkin and Kosilkin, 2019).

Also, as Sorokina (2020) justly notes, investment and commercialization of the genomic research industry is possible with a balance of human rights and non-discrimination, as well as in order to channel most of the profits into the further development of the scientific industry itself and scientific knowledge in the field of the human genome.

We also note that both legislative initiatives and judicial practice are just beginning to form balanced approaches to legal regulation and many questions and problems remain unresolved and are still subject to further development (D'yakov, 2020; Moskovkina, 2020; Ponomareva, 2020; Sorokina, 2020).

In this regard, attention is drawn to the proposal of the Committee on Ethics, Law and Society (CELS) of the Human Genome Organization (HUGO), within the framework of which a number of principles were formulated that, in the opinion of the representatives of the Committee, can form the basis of the regulatory model. The Committee formulated the following principles (Capps et al., 2019):

- social justice, within which the human genome is regarded as the common heritage of humanity, social justice in this case implies the right of every individual to share in the benefits of scientific progress and its technological applications;

- genomic solidarity. This principle implies that genomic research should be a reciprocal exchange between individuals and communities, with researchers, funders, and sponsors, so that all participants (human beings as originators of sequences) share in the benefits of the research through knowledge dissemination and progress, and not just as end-product users, for the reason that may create inequity because of commercial interests and differential access;

- work for the public good. Future regulatory models should be aimed at generating public social benefit and not merely private commercial gains.

These principles, in our opinion, are the most general principles of legal regulation and can be used as the basis for the regulatory model of commercial use of the results of genomic research; nevertheless, in our opinion, they need to be clarified and further developed in relation to specific areas of genomic research.

### **III. Biobanks Activities Issues**

Examples of commercial use of the results of genomic research include the activities of biobanks and economic models of their functioning. Consideration of various approaches to economic models

of the functioning of biobanks will allow us to determine the approaches to the legal regulation of their activities, make assumptions about the legal nature of biobanks.

The variety of forms of activity of biobanks, the goals of their creation, the tasks that their founders set for the activities of biobanks, predetermines the variety of approaches to economic models of biobanks. Biobanking is a separate type of economic activity at the forefront of science, education and modern medical practice (Mokhov, 2018).

Often, a biobank is understood as a repository of various biological samples and materials (cells, tissues) (Mokhov, 2018). Meanwhile, it is important to change the approach — from a purely technical to a legal one, to endow biobanks with subjectivity, which implies licensing, control, and responsibility, to ensure the consistent implementation of the legal principles laid down in Russian legislation, which generally meet modern international standards, at all levels (Kosilkin, 2020).

A biobank is an object in the process of formation, the possible development paths of which can be a stake in numerous and diverse social conflicts unfolding around biobanks between social agents with their specific interests (scientists, doctors, states, investors, donors, groups of civil activists) (Varkhotov et al., 2016).

That is why the need to consider economic models for the functioning of biobanks seems to be the most urgent. In addition, when studying this issue, in our opinion, it is necessary to take into account modern civilizational tendencies affecting all spheres of social relations, including economics, law and others. As mentioned at the beginning of this article, this is a trend aimed at the formation of a post-industrial, information society, a post-industrial, information, digital economy.

When building an economic model of a biobank, it is necessary to take into account the following issues: understanding the market needs for the particular type of biobank under consideration, as well as understanding and efficiently managing the biobank “value chain”, which includes the costs of sampling, tissue processing, storage, management, distribution of samples, infrastructure and administration (Vaught, Rogers, Carolin and Compton, 2011).

Depending on the goals and objectives, there are population biobanks and tissue biobanks, clinical and research biobanks (Hewitt and Watson, 2013; Loft and Poulsen, 1996).

Population biobanks include both epidemiological and clinical samples collected from volunteers without specific inclusion or exclusion criteria (Hubel, Spindler and Skubitz, 2014). Tissue biobanks are a source of data on the health status of the population (De Souza and Greenspan, 2013).

Depending on the owner of the property or depending on the founder, the biobank can be divided into state institutions, private organizations in any organizational and legal form, as well as mixed ones. It should be noted that, as a rule, this also determines the goals of the biobank as an independent structure. The activities of government agencies, as a rule, are not associated with the extraction of profit as the main goal. While the functioning of the biobank as a commercial structure, as a rule, is aimed primarily at making a profit. All this determines the economic models of the functioning of the corresponding structures. At the same time, we note that, for example, in relation to the Russian Federation, state institutions, as essentially non-profit organizations, have the right to carry out income-generating activities, provided that this serves to achieve the goals for which they were created, and if it corresponds to such goals.<sup>5</sup>

The economic models of the functioning of biobanks also differ accordingly. Thus, a biobank created by the state maintains its functioning mainly at the expense of state funds provided for one basis or another (subsidies, grants, donations, government contracts, budget investments, etc.).

A biobank, which functions as a private organization, mainly aims at making a profit, which predetermines the appropriate areas of activity and the need to build a marketing policy, communication with potential clients, minimize costs and expenses if it is necessary to increase margins, etc.

Meanwhile, the following should be noted. Biobank as an organization can pursue research goals, i.e. obtaining new scientific information as a result of analysis and processing of information contained in the biobank itself and attributable to the corresponding biological samples.

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<sup>5</sup> p. 4, art. 50 of the Civil Code of the Russian Federation. Collection of Legislation of the Russian Federation, 1994, No 32, Art. 3301.

At the same time, maintaining the functioning of the biobank as an organization requires certain financial costs, which determines the commercial orientation of the biobank's activities.

Accordingly, in this situation, one can speak of a kind of biobank dualism, a special kind of dialectic that leads to the emergence of an internal contradiction in the activities of the biobank, which, nevertheless, can contribute to the development of this structure and the emergence of new qualities that can be used as competitive advantages in conditions of a market economy.

With regard to the post-industrial, information society, we can also talk about the information economy, in which the productivity and competitiveness of factors or agents (be it an individual, a firm, or a national economy) depends on the ability to generate, process and effectively use information based on knowledge (Tufetulov, 2017).

According to a number of scientists, a characteristic feature of the information economy is the formation of so-called network structures, network relations. The process of formation of the information economy changes the business environment and the dynamics of competition for all economic entities. Network structures and forms of management organize a space of close interaction between various spheres (technological, political, social, cultural) (Lazarev, Lazarev and Khizha, 2005).

One of the brightest technological manifestations of recent times is the blockchain information technology, the so-called distributed ledger technology.

Blockchain is a distributed database consisting of a "chain of blocks", block storage devices are not connected to a common server, the database allows controlling the reliability of transactions without supervision any financial regulators. Blockchain is a distributed and decentralized database formed by participants, in which it is impossible to falsify data due to the historical record and public confirmation of the transaction by all network participants (Fedotova, Yemel'yanov and Tipner, 2018).

Initially, this technology was used to form and circulate so-called cryptocurrencies. Nevertheless, this technology has a number of characteristics that make it possible to use it not only in the financial

sector, but also in other areas of society, for example, for notaries, cadastres, registers of property rights, taxes and benefits, violations and fines, user identification, registration of civil acts, civil status, public services, healthcare, education, art transfer, supplies, fair voting systems, loyalty programs, lotteries, etc. (Nagrodskaja, 2019).

The main characteristics of this technology that determine its attractiveness for use in various spheres of social relations are:

- 1) decentralization;
- 2) anonymity;
- 3) autonomy;
- 4) the use of cryptography;
- 5) adding special time stamps to each transaction (Nagrodskaja, 2019).

The idea of using blockchain technology in healthcare is not completely new. Currently, a number of projects based on the use of this technology are known, which have been successfully implemented and work in real life.

For example, Estonia became the first country to implement blockchain on a national scale. The eHealth Foundation of Estonia has been operating since 2005. In 2016, the eHealth Foundation teamed up with Guardtime, a data security company. Guardtime helped the foundation implement KSI (Keyless signature infrastructure), a blockchain technology that provides large-scale data authentication without relying on a centralized trusted authority. The project now contains over 1 million patient records and patient data. The KSI infrastructure ensures high security of medical data, their safety and integrity (Blockchain technologies application in health care, 2021).

The government of Mongolia, together with FarmaTrust Company, has launched a project to implement a drug tracking system based on blockchain technology, aimed at eliminating drug counterfeiting in the country (Mongolia to pilot blockchain drug traceability system, 2021).

The Novgorod Region became a pilot region in which, for the first time in Russia, Vnesheconombank (VEB) launched a program for monitoring drug circulation in a hospital using a blockchain system. This method of accounting will help fight counterfeiting and leakage of

expensive prescription drugs bought with budget money (Blockchain technologies to help control drugs trade in Nizhny Novgorod, 2021).

The use of blockchain technology is also possible in clinical trials in order to ensure the authenticity, reliability of results and to achieve other goals. Currently, the development of an information system for clinical trials based on blockchain technology is underway by a consortium, which includes the following organizations: National Medical Research Center of Oncology named after N.N. Petrov, National Medical Research Center of Oncology named after N.N. Blokhin, National Medical Research Center for Radiology, Ministry of Healthcare of the Russian Federation, First Saint Petersburg State Medical University named after academic I.P. Pavlov. The participants also include local ethics committees and patient organizations. The information system being created will improve the quality of clinical trials, ensure the availability and security of data, reduce the production time of modern anticancer drugs, and increase the level of technological equipment of the industry as a whole. The system will be validated according to international standards (Belyayev et al., 2018).

Foreign researchers also note the possible positive economic impact of the use of blockchain technology in medicine, healthcare, genomics, which is confirmed by a significant number of scientific studies devoted to this topic (Tandon, Dhir, Islam and Mäntymäki, 2020).

According to some authors, blockchain technology has become a suitable and modern solution for the secure storage and exchange of genomic data (Sami Ullah, Aslam and Arjomand, 2020). According to some studies, the market for the application of blockchain technology in the genomic market may grow at an average annual rate of 66.42 % for the period 2019–2029 (Research and Markets, 2019). Some authors suggest the possibility of using blockchain technology to create reliable systems for storing and processing genetic information (Ozercan, Ileri, Ayday and Alkan, 2018).

With regard to the functioning of biobanks, the use of blockchain technology will significantly improve business processes, increase the reliability of storage, processing and circulation of information, i.e. will make it possible to qualitatively change the means of production. Moreover, the use of blockchain technology will make it more convenient

for users and patients to work with the biobank, and will allow a more flexible use of the institution of informed consent.

Thus, when developing future economic models for the functioning of biobanks, it is advisable to take into account the possibility of using blockchain technology, which will significantly improve the organization of the biobank, rationalize the use of production means, and, consequently, obtain a significant economic effect from the introduction of appropriate technologies. Blockchain technology as applied to the economy of biobanks can be introduced both at the institutional and functional levels, and can be used in the formation of a special kind of regulatory environment for the activities of biobanks.

It is also necessary to note the possible positive effect of using blockchain technology for public administration in the field of biobanking and genomic research in general, in order to develop such a methodology for resolving ethical and other contradictions, which will allow making significant decisions in the field of genomic research in dynamics. In addition, in relation to the legal regulation of genomic research, the use of blockchain technology in the future may allow in real time to resolve controversial issues related to research in a pre-action manner.

An important aspect in the formation of an economic model for the functioning of biobanks is attracting investors to finance the activities of biobanks. In this area, a large number of behavior models are also possible, aimed at ensuring the rights of investors on the one hand, and at ensuring relative independence and a certain level of freedom in the activities of the biobank itself, on the other hand.

Within the framework of this paper, I would like to draw attention to new, only recently emerged, methods of financing activities, the development of which does not go unnoticed and increasingly affects the construction of certain economic models. This is, first, crowdfunding financing.

Crowdfunding is usually understood as such an activity when the relevant activities are financed not by the owner and not at the expense of the state, but at the expense of funds raised by persons in one way or another interested in a particular project.



Crowdfunding projects have been developing at a serious pace lately. According to the report of the research group Massolution, which collected data from 1,250 crowdfunding sites around the world, in 2015 its global volume was estimated at 34 billion US dollars, of which North America accounted for about half – 17.25 billion US dollars. Asia occupied the conditional second place with 10.54 billion US dollars; in Europe, they collected 6.48 billion US dollars (Motovilov, 2018).

For the first half of 2019, the volume of funding using the crowdfunding toolkit amounted to USD 6.923 billion. The Russian crowdfunding market over the past 5 years has grown more than 40 times in terms of funding. If in 2014 the total amount of financing for projects was only 0.3 billion rubles per year, then in 2018 the amount was about 14 billion rubles (according to the Bank of Russia estimates, from 13 to 15 billion rubles), and in 2019 it may reach 16 billion rubles. At the same time, the development of the market does not follow a linear trend, but exponentially. In the next 2 years, it is possible to expect more than a twofold increase in investments in the crowdfunding market, and in a 5-year perspective, according to the Bank of Russia forecast, the volume of crowdfunding financing will reach 1 trillion rubles in year (Neopulo, Popov and Kuksov, 2020).

Crowdfunding, as a way to attract funding, differs from both charity and classic investing. However, it is closely related to the specified methods of financing.

Initially, crowdfunding was formed as a non-investment, gratuitous model, when funds were transferred in the form of a donation (donation-based crowdfunding), as well as a model based on a kind of reward: non-financial or monetary (reward-based crowdfunding). Lending-based crowdfunding and equity crowdfunding have become more complex forms (Motovilov, 2018).

It is also very important to note the phenomenon of crowdfunding, in which fundraising in this way also has a fairly significant marketing effect, i.e. in this way, information about the relevant project is disseminated among a significant number of potential customers, which in the long term outlook can also have the necessary economic effect.

In addition, as a specific type of crowdfunding, one can consider such a method of financing, in which a client receives a service, for

example, information from a biobank, or analysis of certain information contained in a biobank in relation to a specific subject or object at a reduced price, but at the same time, the client provides biobank available and important for the biobank samples or data with certain conditions, allowing the biobank to use such samples or data on a fairly widespread basis.

In the Russian Federation, the Federal Law dated 02.08.2019 No 259-FZ “On attracting investments using investment platforms and on amending certain legislative acts of the Russian Federation”<sup>6</sup> is devoted to the legal regulation of certain types of crowdfunding. This law regulates only one type of crowdfunding, namely investment crowdfunding, or as it is also called, crowdfunding. The law defines the basic concepts in this area, such as an investment platform, an operator of an investment platform, utilitarian digital rights and others, the law determines that the following digital rights (utilitarian digital rights) can be acquired, alienated and exercised in an investment platform: the right to demand transfer thing (things), the right to demand the transfer of exclusive rights to the results of intellectual activity and (or) the rights to use the results of intellectual activity, the right to demand the performance of work and (or) the provision of services. The law defines the requirements for an investment platform, an operator of an investment platform, an investor, a person attracting investments, an investment agreement, etc. The adoption of this law, despite some of its shortcomings, can be generally regarded as a positive fact that can contribute to the development of crowdfunding in the Russian Federation.

It can be assumed that crowdfunding as a way to finance the activities of biobanks is very promising and can receive serious development, given the great demand for the activities of biobanks. When constructing promising economic models for the functioning of biobanks, in our opinion, it is advisable to take into account the possibility of a similar method of financing. At the same time, it is likely that economic models using crowdfunding financing may also imply financing from investors, income from the activities of the biobank

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<sup>6</sup> Collection of Legislation of the Russian Federation, 2019, No 31, Art. 4418.

itself and from other sources. Of course, this kind of financing will not be able to fully ensure reproduction in such a science-intensive and technological sphere of public life as biobanking, but it can be a significant help in financial support of the biobank's activities.

At the same time, when forming models of legal regulation of the activities of biobanks, it is necessary to take into account the approaches indicated above in this article to the formation of economic models of the activities of biobanks, including the possibility of using blockchain technologies and methods of crowdfunding financing. Taking into account the above tendencies will make it possible to form a model of legal regulation that best meets the modern realities of the information, post-industrial society, modern information, digital economy.

#### **IV. Modern Challenges and Definition of Concepts in the Sphere of Legal Regulation of Genomic Research**

In addition to the above factor associated with the formation of the information society, social relations in the field of genomic research are greatly influenced by the practical application of the results of scientific advances in medicine and biology.

The development of modern technologies and modern challenges, such as the possibility of genome editing using CRISPR-Cas9 technology, the possibility of implementing mitochondrial replacement therapy methods and using these methods in practice, the possibility of the so-called intracytoplasmic injection of male germ cells, the ability to examine embryos for the presence of genetic diseases, the relative prevalence of donation of male germ cells, eggs, embryos and the use of the corresponding cells in assisted reproductive technologies have largely affected the spheres of social relations associated with donation and parenthood, which often leads to ambiguous legal situations.

So, in 2019, the following situation was considered in the courts of England: a man (ex-woman), known only as TT, was fertilized with donor sperm in order to conceive a child, named only as YY in court documents. He wants to be called "father" or "parent" of YY on his birth certificate, but because he suffered a pregnancy, he is designated as a mother under the Human Fertilization and Embryology Act 1990

(Human Fertilisation and Embryology Act 1990, 2021). The fact is that TT is transgender and received documents on gender reassignment before treatment, therefore, legally he is a man (Judge calls for law review after trans man gives birth – BioNews, 2021).

Therefore, within the framework of this article, we will focus on the definition of approaches to the formulation of such basic concepts in the field of human reproduction as donation and parenthood.

Approaches to legal regulation in the field of genetic research of human reproduction should ensure a balance of public and private interests, the interests of various actors involved in relevant social relations, a balance between personal and public interests.

To form a full-fledged legal regulation in any area, it is initially necessary to clearly define the concepts that will appear in the normative legal acts devoted to the regulation of the relevant social relations, as well as used in the doctrine.

The formation of the conceptual apparatus is necessary to ensure certainty, accuracy, unambiguity of the legal regulation of the relevant social relations. Scientifically grounded and clearly formulated concepts set the direction of regulation both in positive law and in doctrine, and define the boundaries of such regulation.

The legislation of the Russian Federation contains a definition of a donor of biological material. However, this definition applies only to the field of biomedical cell products, regulated by the relevant law, which does not apply to relations arising from the use of human germ cells for using assisted reproductive technologies, as well as to relations arising from the circulation of cells and human tissues for scientific and educational purposes.<sup>7</sup> With regard to the field of human reproduction, the concept of a donor should be clarified, since the legal status of a donor in the field of human reproduction differs significantly from the status of a donor of other biological materials.

In foreign legal acts (Health & Consumer Protection Directorate-General of the European Commission, 2006; Sabatello, 2015) the concept of a donor is widespread as a person who has provided his

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<sup>7</sup> Federal Law No 180-FZ dated 23.06.2016 (as amended on 03.08.2018) “On Biomedical Cell Products”, Art. 1. Collection of Legislation of the Russian Federation, 2016, N 26 (Part I), Art. 3849.

reproductive cells for medical purposes. In each case there are different options for definitions, which emphasize different aspects.

For example, in the UK, the Donor Disclosure Regulation 2004 No 1511, adopted on June 14, 2004<sup>8</sup> a donor is defined as a person who has provided the sperm, eggs or embryos that have been used for treatment services in consequence of which the applicant was, or may have been, born. At the same time, in the UK Human Fertilization and Embryology Act 1990 (Human Fertilisation and Embryology Act 1990, 2021) there is particular emphasis on the fact that the donor's consent must be obtained for the use of the appropriate cells: A person's gametes should not be used for treatment or non-medical fertility treatment services unless that person has valid consent to their use and they are used in accordance with terms of consent. A person's gametes should not be accepted for use for these purposes, unless that person has actual consent to use them.

A more comprehensive definition of a donor in human reproduction is found in the Children and Family Relationships Act 2015, Section 4 of Part 2:<sup>9</sup>

*“donor”—*

*(a) in relation to a gamete, means-*

*(i) a person who has consented, under section 6 or in the manner referred to in section 26 (1)(b)(ii), to the use in a DAHR procedure of a gamete provided by him or her, or*

*(ii) the donor of a gamete to which section 26 (6) applies, and includes a donor of a gamete that is used in the formation of an embryo that is used in a further DAHR procedure, and*

*(b) in relation to an embryo, means-*

*(i) a person who has consented under section 14 or 16 or in the manner referred to in section 26 (2)(b)(ii), to the use of the embryo in a DAHR procedure or a further DAHR procedure, or*

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<sup>8</sup> 2004 No 1511 The Human Fertilisation and Embryology Authority (Disclosure of Donor Information) Regulations 2004. Available at: [http://www.legislation.gov.uk/ukxi/2004/1511/pdfs/ukxi\\_20041511\\_en.pdf](http://www.legislation.gov.uk/ukxi/2004/1511/pdfs/ukxi_20041511_en.pdf) [Accessed 22.03.2021].

<sup>9</sup> Children and Family Relationships Act 2015. Available at: <http://revisedacts.lawreform.ie/eli/2015/act/9/revised/en/html#SEC26>, <http://www.irishstatutebook.ie/eli/2015/act/9/enacted/en/html>.

*(ii) the donor of an embryo to which section 26 (6) applies.*

As you can see, in this definition, the main emphasis is on obtaining the consent of the donor for the provision of the corresponding cells, and the said Law also states that the donor must provide certain information without fail: his or her name; his or her date and place of birth; his or her citizenship; the date and place at which he or she provided the gamete; his or her contact details (clause 24 (3) part 3).

An analysis of the regulation of donation of reproductive cells in different countries suggests that the donor definition should necessarily reflect the subject of donation, i.e. what specific cells and/or materials are provided (female germ cells, male germ cells, embryos), for what purposes (for example, in vitro fertilization, other assisted reproductive technologies, etc.), subject to the availability of appropriate consent to these procedures, and also subject to the provision of the necessary information. Other required parameters may be reflected in the definition.

Among the rights of the donor, the question of whether the donor has (or can have) any parental rights in relation to children born as a result of his donation is quite controversial.

As a general rule, a donor should not have such rights in relation to children born as a result of his donation. However, under certain conditions, such rights may arise from the donor. Thus, we come to the definition of parenthood. The concept of parenthood, legal ties between parents and children are of great importance not only in terms of ensuring children's rights, but also in terms of property issues, inheritance issues, etc.

In the Russian Federation, for example, Art. 48, 51 of the Family Code of the Russian Federation<sup>10</sup> and Chapter II of the Federal Law dated 15.11.1997 No 143-FZ "On acts of civil status"<sup>11</sup> are devoted to this matters. For example, in accordance with Art. 51 of the Family Code of the Russian Federation, persons who are married and who have given their written consent to the use of the method of artificial insemination or to the implantation of an embryo, in the event that they have a child

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<sup>10</sup> Collection of Legislation of the Russian Federation, 1996, No 1, Art. 16,

<sup>11</sup> Collection of Legislation of the Russian Federation, 1997, No 47, Art. 5340.

as a result of the use of these methods, are recorded by their parents in the birth register. Persons who are married to each other and have given their written consent to implantation of an embryo to another woman for carrying it, can be registered as the child's parents only with the consent of the woman who gave birth to the child (surrogate mother). As we can see, these definitions are rather limited in nature, they only regulate situations that arise in persons who are in a registered marriage, and do not regulate various other situations.

The issues of determining parenthood have been studied in sufficient detail within the framework of the Hague Conference on Private International Law since 2011 (HCCH. The Parentage/Surrogacy Project, 2021). As part of this work, in 2014 the document "Desirability and Feasibility of Further Work on the Parentage/Surrogacy Project" (2021)<sup>12</sup> was approved, which summarizes the work on the project over the past period and formulates proposals for the following periods. The concept of parenthood within the framework of this project is considered in relation to ensuring children's rights in the light of human rights in general, private legal aspects of relationships complicated by a foreign element are considered. Within the framework of the project, definitions of legal parenthood or legal parents are formulated, which are understood as a person (persons) who have acquired the legal status of the child's "parents" in accordance with the relevant law, and who will receive all the rights and obligations arising from this status in accordance with this law. The concept of genetic parenthood or genetic parents is also formulated: a person (persons) who provided their genetic material for conceiving a child. In some languages this is called "biological origin." Within the framework of the project, annual conferences are held, according to the results of which the corresponding reports are adopted.

In parenthood, three main aspects can be distinguished, two of which apply to both men and women, namely: the genetic aspect and the intentional aspect (intentions), and one only to women is the gestational aspect.

Some of the researchers believe that parenthood intent is, in fact, an aspect of parenthood that supports full recognition of parenthood

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<sup>12</sup> Available at: <https://assets.hcch.net/docs/6403eddb-3b47-4680-ba4a-3fe3e11c0557.pdf> [Accessed 22.03.2021].

with the exception of genetic or gestational input or marital assumptions (Storrow, 2002). Nevertheless, in our opinion, it is necessary to take into account various factors and use an integrated approach to the definition of parenthood in the field of reproductive technologies, while, of course, intention is of great importance in this matter.

## **V. Ensuring a Balance of Interests as the Basis for Legal Regulation of Social Relations in the field of Genomic Research**

It seems important from the point of view of the formation of legal regulation in the field of genomic research, to dwell a little on such an issue as ensuring a balance of interests as the basis of legal regulation in this area.

Recently, it is often possible to meet the opposition of human life and health on the one hand and the interests of science and society on the other. Meanwhile, in our opinion, such opposition leads to a negative effect in any case, no matter which of the interests is put at the forefront. It seems that ensuring a balance of interests, both legal and organizational, can be considered as the basis of legal regulation in this area, so I would like to dwell a little on this issue.

Interest is characterized as something objectively significant, necessary for an individual, collective, society, etc. (Philosophical Dictionary, 1980, p. 131). At the same time, interest in law serves as its most important law-forming and law-implementing factor (Kosarenko, 2007).

With regard to the area under consideration, three levels of interests can be distinguished according to the degree of their commonality — these are private interests, group interests and general or, in other words, public interests.

Among the private interests, first, it is necessary to note the interests of specific people, individuals who, within the framework of the considered social relations, can act in various qualities — a patient, a participant in scientific research, etc. It seems that the main, legally significant direction, vector of private interests is the provision of individual rights and freedoms of individuals.



With regard to group interests, the interests of various social groups or group social players can be named as subjects. In the area under consideration, these include, for example, the interests of business, entrepreneurs, incl. large medical and/or pharmaceutical corporations, which are characterized by an independent focus, first, on maximizing profit and often come into conflict with the interests of individuals and even with public interests.

Public interests can be attributed to the state, the purpose of which should be, first, to ensure the stability and security of the development of society, to maintain public consensus and balance, which determines the direction, vector of interest in this case.

Thus, it is obvious that there are at least three levels of interests, which often come into conflict with each other and need to find a balance.

It seems that when determining approaches to determining the balance of interests in this case, the following factors should be taken into account.

1. The dynamic development of the regulated sphere of social relations, due to the explosive development of technologies in the field of genomic research in recent years.

2. Extreme sensitivity of the relevant sphere of social relations, including in relation to a specific person, especially when it comes to genomic research in the field of human reproduction.

3. A significant number of relations between subjects of different states in the considered sphere of social relations.

4. Close connection of the considered sphere of social relations with human rights law as an independent branch of international law.

5. Significant influence of ethics and morality on social relations in this area.

Taking into account these factors, it can be assumed that in order to ensure a balance of private, group and general interests, it is necessary to establish sufficiently clear and developed norms in positive law, including at the level of international law and the law of interstate integration formations, it is necessary to use a symbiotic regulator, including both legal norms and norms of a different social nature. In addition, there is a need for a credible and reliable mechanism that would make it possible to promptly resolve emerging issues and contradictions of both ethical and legal nature.

## VI. Conclusion

Based on the results of considering the issues indicated in this article, the following conclusions can be drawn.

The development of an informational, post-industrial society, informational, digital economy is an important factor that has determined the emergence of new areas of knowledge, scientific disciplines, new challenges, including in the field of genomic research. In particular, such a scientific discipline as bioinformatics has appeared and is rapidly developing. Legal regulation of social relations in the field of bioinformatics should take into account the substantial dualism of information and, in this regard, may be a combination of international legal regulation and (or regulation at the level of regional integration formations) and harmonization of legislation and legal regulation of various states.

Biobanks are the most pronounced industry in the field of the implementation of the results of genomic research, which has been rapidly developing lately, which requires the formation of a scientifically based model of legal regulation of the activities of biobanks taking into account the current state of economic relations.

At the same time, it is advisable to take into account the possibility of using blockchain technology, which can significantly improve the organization of the biobank, rationalize the use of means of production, and, therefore, obtain a significant economic effect from the introduction of appropriate technologies. Blockchain technology as applied to the economy of biobanks can be introduced both at the institutional and functional levels, and can be used in the formation of a special kind of regulatory environment for the activities of biobanks.

It is also necessary to note the possible positive effect of using blockchain technology for public administration in the field of biobanking and genomic research in general, in order to develop such a methodology for resolving ethical and other contradictions, which will allow making significant decisions in the field of genomic research in dynamics. In addition, in relation to the legal regulation of genomic research, the use of blockchain technology in the future may allow in real time to resolve controversial issues related to research in a pre-trial manner.

Crowdfunding, as a way to finance the activities of biobanks, is very promising and can get serious development, given the great demand for the activities of biobanks. When constructing promising economic models for the functioning of biobanks, in our opinion, it is advisable to take into account the possibility of a similar method of financing. At the same time, it is likely that economic models using crowdfunding financing may also imply financing from investors, income from the activities of the biobank itself and from other sources. Of course, this kind of financing will not be able to fully ensure reproduction in such a science-intensive and technological sphere of public life as biobanking, but it can be a significant help in financial support of the biobank's activities.

Social relations in the field of genomic research are greatly influenced by the practical application of the results of scientific advances in medicine and biology. The development of modern technologies and modern challenges, such as the possibility of genome editing using CRISPR-Cas9 technology, the possibility of implementing mitochondrial replacement therapy methods and using these methods in practice, the possibility of the so-called intracytoplasmic injection of male germ cells, the ability to examine embryos for the presence of genetic diseases, the relative prevalence of donation of male germ cells, eggs, embryos and the use of corresponding cells in assisted reproductive technologies, largely affected the spheres of social relations associated with donation and parenthood, which makes it necessary to propose approaches to the formulation of relevant concepts as a basis for legal regulation in the specified area.

To ensure a balance of private, group and general interests, it is necessary to establish sufficiently clear and developed norms in positive law, including at the level of international law and the law of interstate integration formations, it is necessary to use a symbiotic regulator, including both legal norms and norms of a different social nature. In addition, there is a need for a credible and reliable mechanism that would make it possible to promptly resolve emerging issues and contradictions of both ethical and legal nature.

Legal regulation of genomic research presupposes a comprehensive regulation of relevant social relations, within which it is necessary to

take into account modern challenges, achievements of other sciences and disciplines in order to propose models of legal regulation that most closely meet the needs of modern society.

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### Information about the author

**Alexey V. Kubyshkin**, Cand. Sci. (Law), Advocate at Advocate's Office "SanctaLex" of the Moscow City Bar Association, Partner of Scientific Collaboration "Legal Genomics Developments Alliance (LeGenDA)"

2/1, build. 4 Talalikhina St., Moscow, 109147, Russia

[a.kubyshkin@gmail.com](mailto:a.kubyshkin@gmail.com)