

Legal regulation of human genome editing in the Russian Federation



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Introduction

The development of modern technologies has created new opportunities for carrying out genetic research and genome editing. On the other hand, scientists and potential users faced challenges, concerning civil and public regulations of genome editing and its clinical application.

In Russian normative legal regulation system, according to Art. 3 of the Federal Law of July 5, 1996 № 86-FL «On State Regulation in the Field of Genetic Engineering», the regulatory legal framework for genetic engineering, including genome diagnostics and gene therapy, consists only of federal laws and laws of the constituent entities of the Russian Federation.

This means that international legal regulation in this area is practically not applied at the territory of the Russian Federation.

Shortcomings of Russian legislation in the field of genetic engineering



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- The use of genomic research in Russian medicine is insufficiently regulated by law;
- There are no rules for taking umbilical cord blood;
- There are no qualification requirements for specialists engaged in genetic engineering;
- The status of pre-implantation embryos is not legally fixed.

Advantages of Russian legislation in the field of genetic engineering

- The Decree of the President of the Russian Federation of November 28, 2018 № 680 «On the Development of Genetic Technologies in the Russian Federation» sets the tasks for the accelerated development of genetic technologies, including technologies for genetic editing, ensuring the development of biological preparations, diagnostic systems and immunobiological agents for the healthcare sector, biotechnology for agriculture. economy and industry, as well as improving measures for the prevention of emergencies of a biological nature and control in this area.
- The Resolution of the Government of the Russian Federation of April 22, 2019 № 479 on «Federal Scientific and Technical Program for the Development of Genetic Technologies for 2019 – 2027» is developed. The Resolution consolidates the transition to personalised medicine and defines principles of development of the pharmacological industry.

Intellectual property rights on the results of genetic research and genomic editing products



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- The products of genetic engineering in Russian law, on the one hand, is considered as a product of science subjected to copyright, and on the other hand, a database, since these data are likely to be processed and systematised.
- The results of genomic editing can also be registered in the Russian jurisdiction as objects of patent law – inventions.
- An effective way for genetic researchers in Russia would be to use the legal regime «know-how», which allows obtaining legal protection for the results of genomic editing, and at the same time do not to waste resources on state fees.

The use of any of the described approaches to the creation of intellectual property for the results of genomic editing requires compliance with the provisions of the Federal Law of July 27, 2006 №. 152-FL «About Personal Data»

Legal regime of genetic information in the Russian Federation

- The main normative act in the field of information circulation in the Russian Federation is the Federal Law of July 27, 2006 № 149-FL «On Information, Information Technologies and Information Protection», which allows to consider information as an object of civil, public and other legal relations.
- To determine the legal regime of information obtained in the framework of genetic research and genomic editing, it is necessary to take into account the additional regulatory framework governing work with laboratory animals, if the experiments are based on working with them.
- When carrying out genetic research on humans, the regulatory framework in the Russian Federation is based on Federal Law № 323-FL of 21.11.2011 «On the Basics of Health Protection of Citizens in the Russian Federation».
- It should be borne in mind that genetic information, including information concerning human biological rhythms, according to Article 11 of the Federal Law of the Russian Federation of July 27, 2006 №. 152-FL «On Personal Data», can be attributed to biometric personal data.
- Such information, according to the legislation, incorporates the physiological and biological characteristics of a person, on the basis of which it is possible to establish the identity.

In the context of optimisation the legal regime for the results of genomic research, it is proposed:

- To use the normative construction of documented information to implement the legal regime of «know-how» secrets related to the results of genomic research;
- To set frameworks of the information legislation and civil law in relations concerning the genomic research;
- To legislate the possibility of applying the legal regime for databases to deposit information collected as a result of genomic research;
- To overcome difficulties to deal with transnational problems of human genome editing with Russian national legislation; rather efforts should be made to reach international consensus on this subject.