Research article
UDC 34:004:342.721:612.6
EDN: https://elibrary.ru/tklbsa
DOI: https://doi.org/10.21202/jdtl.2024.27

Human Genome Editing: Managing Technological Risks through Legal Means

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Keywords

digital technologies,
genetic editing,
genetic technologies,
human genome,
law,
legal liability,
legislation,
reproductive technologies,
risk-based approach,
technological risk

Abstract

Objective: to determine theoretical approaches to the legal regulation of reprogenetic editing, taking into account the risk-oriented approach and the practice of regulation of such breakthrough technologies in different jurisdictions; to outline further regulatory and managerial steps to be taken for the technology development.

Methods: general scientific methods of analysis and synthesis, classification, system and functional approaches; specific scientific methods: formal-legal, comparative-legal, and historical-legal.

Results: the research shows the possible approaches to the regulation of genetic editing for reproductive purposes. The considered variants are evaluated from the viewpoint of risk-oriented approach; conditions and peculiarities of various regulatory mechanisms' application are determined; the current Russian regulation in this sphere is assessed. The analysis allows concluding that the prohibition or significant restriction of the developing technology of reprogenetic editing has no irrefutable grounds. Moreover, it may lead to the results opposite to those declared by its proponents. In this regard, it is necessary to develop the discussion in a constructive and iterative way and involve all stakeholders in it, including the scientific community.

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Scientific novelty: the international practice of legal regulation of reprogenetic technologies within different jurisdictions was generalized and conceptually interpreted; the natural scientific arguments in assessing the implemented regulation effectiveness were analyzed. This not only allows systematically considering the current and hypothetical risks of genetic technologies' development and use, but also provides an opportunity to use a risk-oriented approach to the analysis of legal regulation of genome editing technologies. The next step in comprehending the phenomenon of genetic editing becomes possible.

Practical significance: the study results can be used for building further constructive dialog on applying legal mechanisms to human genome editing. The study can also be a basis for iterative approach in the future discussion.

For citation

Troitskaya, A. A., & Sharlovskiy, K. A. (2024). Human Genome Editing: Managing Technological Risks through Legal Means. *Journal of Digital Technologies and Law, 2*(3), 521–543. https://doi.org/10.21202/jdtl.2024.27

Contents

Introduction

Genome editing is one of the technologies that has progressed markedly due to advances not only in molecular biology but also in digital tools (Atimango et al., 2024; Pombo, 2011; Wilson, 2023; Tan et al., 2023; Sharif et al., 2023). It is because of these tools that big data on nucleotide sequences, genetic expression, gene interactions with aligned amino acids, etc. could be processed in genetics (Balashenko, 2016). The same applies to the results of CRISPR technologies application for genome editing.

There are different types of human genome editing. Not only from the biomedical, but also from the legal viewpoint, there is a significant difference between editing for medical

and non-medical purposes, as well as somatic cell editing, affecting only a particular patient, and editing of a germline, the alteration of which can manifest itself in future generations (Yu et al., 2012).

In Russia, the legal regulation of inheritable editing of the human genome for any purpose remains uncertain, while a number of ethical issues in this area remain unresolved. In fact, inheritable editing is carried out at the level of fundamental research (albeit with a lack of control over it), and is not carried out for reproductive purposes. Meanwhile, the development of this biomedical sphere should be as safe as possible both for the individual participants (donors of genetic material, potential parents and children, and researchers themselves) and for the population as a whole. Such development requires a clear legal framework to ensure not only predictability but also programmable improvement of the technology, procedures, and results of its application.

The article is organized as follows. First, it will present the current state of human genome editing in Russia, focusing on the risks usually associated with the technology and the existing (actually, rather non-existing) legal norms related to it. Then, we will consider possible specific regulatory mechanisms that could ensure an adequate combination of genetic and reproductive technologies for strictly medical purposes, with appropriate oversight by public authorities and the scientific community. On this basis, conclusions will be drawn regarding the prospects for legal regulation of the technology in Russia.

1. Human genome editing: current situation in Russia

1.1. Biomedical component

At its core, genome editing is a purposeful alteration of an organism's DNA by adding, eliminating, or translocating genetic material. As such, it can be applied to a wide variety of organisms and is therefore in actual or potential demand in fields ranging from agriculture and industry to health care and biosecurity (Asquer & Morrison, 2022). The most serious expectations were related to the CRISPR-Cas9 editing technology. According to some descriptions, it claimed to be relatively (compared to other methods such as viral vectors, zinc finger nucleases (ZFNs), or TALENs) accuracy, efficiency, and cheapness to use (Barnett, 2017). However, one could notice that the cheerful assessment was somewhat refuted by data on actually performed experiments with a very low success rate at the output (Liang et al, 2015; Ma H. et al., 2017; Ledford, 2017). This method was claimed in the sensational story of the Chinese researcher He Jiankui, who changed the gene encoding the protein that allows HIV to enter the body and transplanted (against

the existing legal prohibition in China) the altered embryos into the uterus. The result was the birth of two girls (and criminal punishment for the researcher)[1].

The Russian Federation also undertakes fundamental research involving embryonic genome modification. The work by D. V. Rebrikov's group became famous, especially after numerous publications in the media about the researcher's willingness to use the technology for reproductive purposes, following the Chinese scientist[2]. It should be clarified that over time the group's focus was shifted from created immunity to some HIV variants (which, although it had obvious medical purposes, but still meant not curing the existing disease as such, but rather acquiring a "superpower" to avoid infection[3]) to hereditary hearing loss. At first glance, the disease's autosomal recessive type of inheritance does not require such drastic measures as genetic editing. The disease manifests itself only in the homozygous state, i.e. when both copies of the gene located on homologous autosomes are defective. According to Mendel's law, even if both parents are the disease carriers, the probability of giving birth to a sick child is 25 % and can be offset, e.g., by vitro fertilization and preimplantation genetic testing to select embryos without the disease[4]. In fact, the situation changes significantly when the sociocultural aspect is also taken into account. If families are created within a community of people with a hereditary hearing loss (which is often the case), a couple may not have a single embryo without the disease. In such a case, editing looks like a counteraction to the disease of the future offspring and, in addition, in a situation with no clear alternatives.

Nevertheless, to date there has been no explicit approval from the public authorities in Russia to conduct editing for reproductive purposes[5]. In the absence of such approval,

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1 See, e.g.: Cyranoski, D. (2018, November 28). CRISPR-Baby Scientist Fails to Satisfy Critics. Nature. https://clck.ru/3DrtT2

2 See, e.g.: In Russia they create children with the altered DNA. How this threatens the country. (2019, June 14). RIA Novosti. https://clck.ru/3DrtV2

3 Thus, in addition to all other criticisms of He Jiankui, it produced additional reproaches for moving towards non-medical goals of creating offspring with given characteristics (the problem of so-called designer babies). See, e.g.: Chinese scientist who produced genetically altered babies sentenced to 3 years in jail. (2019, December 30). Science. https://clck.ru/3DrtWp

4 The construct is certainly not free from criticism, primarily of an ethical nature (Henaghan, 2006), but it is quite legally applicable, including in Russia. See: Order of the Russian Ministry of Healthcare No. 803n of 31.07.2020; para. 10 of the Order explicitly provides for such indications for ART as "hereditary diseases for the prevention of which pre-implantation genetic testing (hereinafter – PGT) is necessary, regardless of fertility status".

5 In 2019, the Ministry refused to issue such an authorization, referring to unexplored potential complications in the short and long term, as well as the WHO position. See: the Ministry of Healthcare said that it is premature to issue an authorization to alter the human genome. (2019, October 6). TASS. https://clck.ru/3Drtgc

as far as can be seen, editing does not go beyond the stage of fundamental research. This is facilitated, among other things, by the uncertain legal consequences for Russian scientists if they decide to follow their Chinese colleague.

1.2. Legal component

The legal component of the development and application of the discussed technology in Russia remains uncertain. Not that there is no regulatory framework in the field of genetic engineering at all, but there are no clear enough regulations on making inheritable changes to the human genome.

In particular, the Federal Law of July 5, 1996 No. 86-FZ "On state regulation in the field of genetic engineering"[6] (with subsequent amendments) specifies in Article 1 that "the order of genetic engineering and application of its methods to human beings, tissues and cells in human organism, except for gene diagnosis and gene therapy (genotherapy), is not the object"[7] of its regulation. At the same time, according to Article 2, gene therapy (genotherapy) is understood as "a set of genetic engineering (biotechnological) and medical methods aimed at introducing changes in the genetic apparatus of human somatic cells for the treatment of diseases"[8]. Since it explicitly refers to somatic cells only, the introduction of changes in the germ line (inheritable changes proper) is not explicitly regulated by this law.

The question of where embryos for fundamental research may or may not come from deserves special attention. In this context, the 1997 Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine is often cited. According to its Article 18, "the creation of human embryos for research purposes is prohibited"[9]. This norm seems quite unambiguous, and in two aspects: it prohibits the creation of embryos specifically for research and does not prohibit the use of those left over from the use of assisted reproductive technologies. In this article we deliberately do not focus on discussing the risks, including ethical ones, arising in this regard, because this is the subject of another detailed publication (Troitskaya, 2022). However, it is easy to see that if it is allowed to create embryos in vitro and test them, and if it is not prohibited to dispose of embryos deemed unsuitable or unclaimed for transplantation (and this is the case in Russia),

6 Federal Law of July 5, 1996, No. 86-FZ "On state regulation in the sphere of genetic engineering". Collection of legislation of the Russian Federation. 1996. No. 28. Art. 3348.

7 Ibid

8 Ibid

9 The Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine of 1997. https://clck.ru/3EBHyX

then the ethical challenge of conducting research on such embryos (again with subsequent disposal[10]) does not seem any more daunting in comparison.

However, the Russian state is not a party to this Convention, and the situation should be clarified accordingly. In the Russian legal space, it is not prohibited to use embryos unclaimed within ART; moreover, there is no explicit prohibition to create them specifically for research. Federal Law No. 180-FZ of June 23, 2016 "On biomedical cell products" prohibits to create human embryos for the production of such products, as well as to use for these purposes the biological material obtained by interrupting or disrupting a human embryo or fetus development. That said, the definition in the same law begs the question of whether an edited embryo is a biomedical cell product. According to the definition, a biomedical cell product is a complex consisting of cell line(s) and auxiliary substances or cell line(s) and auxiliary substances in combination with state-registered medicinal products for medical use, and/or pharmaceutical substances included in the state register of medicinal products, and/or medical devices. Although an embryo may be a source of a cell line, it is not a cell line itself, according to the available definitions[11]. We also believe that in the case of edited embryos the second criterion for classifying the product as a biomedical cell product is not met – namely, the embryo does not include auxiliary substances and/or medicines, pharmaceutical substances, medical devices. In addition, the law specifically states that it does not apply to the use of human sex cells for the purposes of assisted reproductive technologies, as well as to the relations arising from the circulation of human cells and tissues for scientific and educational purposes. Accordingly, the above prohibition

10 As will be shown further, the legal order, allowing embryo experimentation but not the transfer of modified embryos into the uterine, also prohibits the embryos development in vitro beyond a certain period of time, namely, 14 days. This time limit was the result of a consensus reached back in 1979 at the suggestion of the USA. The logic was as follows: up to this point, an embryo can divide into two (resulting in identical twins) or be absorbed by another embryo (in the case of multiple pregnancies); therefore, the emergence of a specific individual before 14 days is out of the question. Recently, however, one can notice a revitalization of the debate allowing a change in this consensus and extending the existence of embryos to 21 or even 28 days. As far as one can understand the arguments of the proponents of extending the time limit, their concern is not centered on some fundamentally new understanding of embryogenesis; it is mainly about having the time (and a developing research object) to better study the consequences of the adjustments made to the genome, to see the slightly more distant effects of editing on the embryo cells and tissues, and in the long run to more reliably control the progression to healthy offspring in humans. See: (McCully, 2021).

11 The Federal Law defines a cell line as a standardized population of cells of the same type with reproducible cellular composition, obtained by withdrawal of biological material from the human body and subsequent cultivation of cells outside the human body. Other definitions are also found in scientific literature, e.g.: a cell line is "a population of cells obtained from primary culture by increasing the number of cells after several generations with a predominance of cells or differentiation lines with a high growth rate and high homogeneity of the cell population". See: (Cherkasova & Brilkina, 2015).

to create embryos for the production of biomedical cell products does not affect the research we are interested in in this case.

The already mentioned Order of the Ministry of Healthcare No. 803n indicates the possibility of diagnosing and storing gametes and embryos, but does not regulate their editing and even less creating embryos for the development of relevant technologies. This is not surprising, since its object is assisted reproductive technologies, not fundamental research.

It seems that in such a situation, the determination of the sources of embryos for research is left to the discretion of a particular research team, and the research per se follows a logic determined by its supervisor.

As for the responsibility in case the edited embryos are transferred into the uterine of a woman (assumingly consenting), it remains not quite clear. Article 235 of the Russian Criminal Code stipulates punishment for medical activities performed by a person who does not have a license for this type of activity, provided that such a license is mandatory, if this has caused harm to human health or (a separate corpus delicti) death by negligence. Article 235 is applicable in the case when editing and transplantation of the edited embryo was carried out outside a medical organization that has the necessary license. In the context of genome editing, it must be a license for medical activity, which provides for the performance of works (services) in genetics and laboratory genetics.

The objective side of the described crime, in addition to carrying out activities without a license, also includes the mandatory infliction of harm to health. Apparently, Article 235 would not be applicable in a situation where the editing went according to the intended plan, spared the future child from the disease and caused no harm. The editing may not be precise and/or effective enough, but how exactly can one prove that specific mutations are a side effect of the editing? Also, in some cases, they may show up at a later stage, after embryo transfer, during prenatal diagnosis. Who will be responsible if a woman decides to prolong her pregnancy and gives birth to a child who is not quite healthy? The list of such questions can be continued. This is not to mention the fact that even a clearly stated prohibition on transferring edited embryos into the uterine can be relatively easily circumvented. By agreement between the doctor and the parents, the fact of editing may be concealed and the genetic variant, which was not expected theoretically but appeared in the end, may be explained by a random miraculous mutation. In fact, who and how would be able to refute this?

The Criminal Code also establishes liability for the provision of services, including medical services, that do not meet safety requirements (Article 238 of the Russian Criminal Code). The objective part of the crime is the provision of services that do not meet the requirements for the safety of life or health of consumers. At the same time, the corpus delicti is formal, i.e. the presence of damage to the health of a particular consumer (patient) is not included in the circumstance in proof (except the specific corpus delicti established by parts 2 and 3 of Article 238 of the Russian Criminal Code). It can be assumed that the provision of any

medical service will be recognized as not meeting safety requirements if it is not provided for by the standards and procedures for the provision of medical care and is not conducted as part of a clinical trial or clinical approbation (Art. 36.1 of the Federal Law of November 21, 2011, No. 323-FZ "On the fundamentals of health protection of citizens in the Russian Federation"). For example, the described case of embryo genome editing for the purposes of subsequent transplantation into the uterine involves applying the developed and previously unused methods of prevention, diagnosis, treatment and rehabilitation in the provision of medical care to confirm evidence of their effectiveness. This must be carried out exclusively in the course of clinical approbation. Among other things, it is necessary to obtain the approval of the ethics committee for using the method and the permission of the Ministry of Healthcare for the clinical approbation, which should specify in which medical organizations, on how many patients and in what order such approbation will be carried out. It is obvious that this authorization procedure was introduced to ensure the safety of patients when applying innovative treatment schemes/methods. The failure to comply with the authorization procedure and the genome editing without such authorization may in itself indicate that the service does not meet safety requirements (or at least allows presuming that safety requirements are not met).

The case is not much different at the principle level if we evaluate the norms of the Russian Code of Administrative Offences (the CAO RF). There are general norms relating to the implementation of activities without a license (Art. 14.1 of the CAO RF) and provision of services of improper quality (Art. 14.4 of the CAO RF). They interpret the quality of medical services as compliance with the relevant procedures for the provision of medical care and clinical recommendations (see part 2 of Article 64 of the Federal Law "On the Fundamentals of Health Protection of Citizens in the Russian Federation"), etc. There is also a special norm stipulating liability for offenses committed in the field of genetic engineering: Article 6.3.1 discloses the corpus delicti as "the use of genetically engineered organisms and (or) products obtained using such organisms or containing such organisms, which have not passed state registration if the state registration is provided for by the above legislation [this assumingly refers to the Federal Law "On state regulation in the field of genetic engineering", which, as noted above, does not apply to embryo editing – Authors], or the validity of the state registration certificate has expired, or the use of genetically engineered organisms not in accordance with the purposes for which they are registered, or violation of special conditions of using genetically engineered organisms, including when producing specific type of products"[12]. It is unlikely that the creators of this norm had in mind the situation of embryo editing for reproductive purposes that we are discussing, and there is no other special norm for this situation in the Code.

[12] Code on Administrative Offenses of the Russian Federation. https://clck.ru/3EBJCC

Separate questions arise in the area of civilistics. What can be the commercial potential of development (with prospects of practical application) of genetic editing technology, if Article 1349 of the Russian Civil Code establishes that "methods of modification of genetic integrity of human germ line cells"[13] cannot be the objects of patent rights (although it is clear that the development of these methods per se is not prohibited by any act)?[14]

As a result, Russia faces a situation in which inheritable editing of embryos is not prohibited at the level of fundamental research, although the procedures for controlling the emergence of embryos for these purposes are not at all clear-cut, and the commercial component of potential investments in this area remains "curtained"; as for inheritable editing for reproductive purposes, it remains completely uncertain in terms of legal consequences for its "authors".

However, it seems that the current technological advances, as well as ethical, social and biological concerns of varying degrees of intensity, require from the legislators not to maintain the twilight zone, but to facilitate controlled development in the area in question. Without pretending to absolutize any ideas, let us present possible moves in this direction.

2. Potential regulation mechanisms

In presenting the management tools, we will be guided by the Framework for Governance of Human Genome Editing published in 2021 by the World Health Organization[15], which, along with other scenarios (prenatal and postnatal somatic cell editing), contains scenarios related to inheritable changes. We will also consider the available experience of the countries for which the issue of inheritable editing is relevant in principle, due to their level of technological development, and which have some experience in regulating this sphere. In this regard, we should specially emphasize that the progress of other legal orders in human DNA editing the technology is far from being as modest as is sometimes believed[16].

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13 Civil Code of the Russian Federation. https://clck.ru/3EBJ6X

14 A competent analysis of the objections raised against patenting genes can be found in the literature (negative consequences of patent protection of such objects for public health and scientific research; the special nature of the gene as a part of the human body and the common heritage of mankind; lack of patentability). See: (Vorozhevich, 2020). Note, however, that some authors discuss the patenting of not the modified gene as such, but the ways to modify it (see, e.g.: Decision of the Intellectual Rights Court of 15.06.2020 in case No. SIP-960/2019). In this case, especially if the state is involved in these relations (as discussed below), all or at least some of the above objections will be removed.

15 WHO. (2021, July 12). Human Genome Editing: a Framework for Governance. https://clck.ru/3DrtyJ

16 See in detail: (Baylis et al., 2020). The study covered 106 countries. As the authors demonstrate, 96 of them have documents (legislation, executive acts, guidelines, codes or international treaties) related to genome editing of early embryos or gametes. Some countries prohibit laboratory research on germline editing (Austria, Croatia, Germany, etc.), some allow it (Ireland, Norway, Japan, United Kingdom, United States, etc.). According to the authors, the use of inheritable editing for reproductive purposes is not authorized in any of the countries studied, although some of them allow the formula "prohibition with exceptions" (Belgium, Italy, etc.), which, of course, is particularly impressive.

In doing so, we take for granted that the priority goal-setting in this sphere includes the development of ideas about the role of genes (as well as their complementary action, the effects of epigenetic factors, etc.). Another priority is the prospect of improving the health of specific patients and future generations of human beings with full respect for their dignity. Moving towards these goals requires an understanding and consideration of the risks (occurring also under uncertainty) that may lie behind particular technologies. In a sense, these ideas can be considered "left aside"; that is, we recognize them and can apply them to all of the above, but no longer specifically repeat them.

2.1. Basic concepts

In a situation where the creation of legal norms adequate to the current challenges is already stalled, it is tempting to skip the stage of discussing key values that would guide future regulation and governance in the field of human genome editing. Nevertheless, it is this stage that should be given attention in the first place. The following starting points could be emphasized here:

– the need to develop fundamental genetics and related fields, in order to understand how the human genome functions, even in the absence of immediate pre-understood applied implications of this knowledge;

– awareness of the link between the development of science and the provision of individual dignity. It results in the desire to improve life quality and the respect for individual autonomy. In practice, it requires an understanding of what exactly is meant by autonomy in the field of genetic inheritance (understandably common to the population) and what kind of improvement in life quality we can talk about. However, it is already clear that medical goals (even those related to obtaining the ability to resist a disease and not only to cure it) are less of a challenge than the "design" of people with predetermined characteristics not linked to medical issues;

– the need for biosecurity. This, however, must be coupled with the idea that genetic editing technology does not emerge in a vacuum, but in the face of a wide variety of factors that affect the genome even without editing (among them, the long-standing use of medical advances that make it possible to maintain a wide variety of gene combinations in the population, including those that lead to disease manifestation; man-made disasters; changes in the system of environmental relations; new types of weapons, etc.).

This list can be continued to include ideas arising from those already voiced. First of all, it concerns the ideology of transparent, accountable and responsible (both on the part of researchers and public authorities) actions, which is promoted by WHO[17]. Admittedly, in WHO wordings it does correlate with expectations of adequate resources and opportunities for scientists and the public to benefit from technological progress[18].

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17 See: Human Genome Editing: a Framework for Governance. § 14.

18 See: Ibid. § 19.

2.2. Legal frameworks

As foreign experience shows, the overdue need for regulation results in the legislative power creating a comprehensive act which covers, among other things, genome editing. There are two noticeably different examples. The British Human Fertilisation and Embryology Act 1990 with subsequent amendments[19] and clarifications added at secondary rule-making[20] has an independent and clearly delineated subject of regulation. It contains norms on human embryos and any subsequent development of such embryos; prohibition of certain actions in relation to embryos and gametes and on the creation of a special body – Human Fertilisation and Embryology Authority. This Act is linked to other acts, including those on surrogacy, but is itself fully and consistently organized around its subject matter. The French Bioethics Act of 2021[21], a much more challenging reading, is essentially a massive list of amendments to other acts, most notably the Public Health Code, although it carries an explicit desire to address a range of bioethical issues, including those relating to the exercise of reproductive rights.

It is obvious that when moving from scratch in the issue of inheritable human genome editing, both ways (creation of a new independent act or making additions to the existing Federal Law 2011 "On the fundamentals of health protection of citizens in the Russian Federation") are possible. Also possible is the path that has been followed so far in the regulation of assisted reproductive technologies – an order of the Ministry of Healthcare with the most basic guidelines in this Federal Law. Moreover, it seems that this way may prove to be in a certain respect[22] more productive for achieving, first of all, professional consensus on a number of issues. After all, both British and French laws, while allowing manipulation on embryos, equally prohibit the transplantation of an embryo with altered nuclear genes[23] for reproductive purposes. Assumingly, in Russia, too, this issue can be clarified in the norms of different levels, especially if these norms are clear-cut and correlate with the provisions of the Criminal Code and the Code of Administrative Offenses.

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19 Human Fertilisation and Embryology Act 1990. https://clck.ru/3DruCm; especially notable are the changes of 2022, stipulated by the Health and Care Act 2022. https://clck.ru/3DruDn

20 Human Fertilisation and Embryology (Research Purposes) Regulations, 2001.

21 Loi n° 2021-1017 du 2 août 2021 relative à la bioéthique. https://clck.ru/3DruFq

22 However, one should also keep in mind the flip side of the coin when using such an approach: the introduction of general rules by executive acts implies the possibility of a one-time cancellation or change of such rules. This makes the situation poorly predictable, including for both potential investors and research teams and medical organizations.

23 With regard to British legislation, it allows the use of donor mitochondria (and the relatively small number of genes it contains) in reproductive technologies. Nevertheless, the use of donor organelle, although related to the creation of "genetically modified" children, is not in biomedical terms the same as genome editing.

Hence, the more difficult questions actually lie less in the form than in the content; namely, in determining within what limits, with what procedures and resources one may carry out fundamental research in embryonic or gamete genome editing. Let us name the substantive aspects:

– the constitutionally and statutorily significant purposes of such research;

– the (probably closed) list of indications for editing;

– the expected fundamental or practical benefits to society (versus the substantively identified risks);

– the procedures for raising private or public funds for the research;

– the sources of the actual material involved in the research, especially when embryos are involved;

– the feasible, necessary for the research, and yet ethically acceptable time limits for the edited embryo development;

– the controls over the research conduct and the result quality (publications, possibility of verifying the results, as well as other ex ante (e.g. authorization, licensing, etc.) and ex post (controls, etc.) measures;

– the degree of the true results openness to others and the possibility of their competent discussion, including scientific verification and criticism;

– the degree of openness of genuine results to others and the possibility of their competent discussion, including scientific verification and criticism;

– the features of protection of researchers' intellectual rights for the subsequent commercial application of their results;

– the extent to which available international standards and foreign practices are taken into account.

These are the issues that could be a "starting grid" for the development of the most concise, and even more so a detailed system of regulation in the sphere of inheritable genome editing.

2.3. Management and control

Judging by the available reports, D. V. Rebrikov's team interacted with the Russian Ministry of Healthcare when trying to calculate the "limits of the possible"[24]. The Ministry of Healthcare includes the Department of Science and Healthcare Innovative Development, which, in turn, can interact with the Ministry of Science and Education. By the Order of the Russian Ministry of Healthcare of December 30, 2020, No. 1416, this Department is responsible for the implementation of measures aimed at the innovative development of healthcare and certain priority areas of medical science, including biomedical and genetic technologies. Thus, in principle, there is no vacuum in this sphere in executive system as

[24] What does Rebrikov want? (2019, October 22). PCR.news. https://clck.ru/3EBKYs

there is in legislation. Nevertheless, departmental acts do not stipulate the exact procedures of organization of fundamental research on inheritable human genome editing (except allocation of grants from some foundations), control and evaluation of its results.

Again, from foreign experience we can see various possibilities of organizing management and control. For example, in Great Britain, the Human Fertilisation and Embryology Authority is entitled to issue a license for fundamental research. A prerequisite for applying for such a license is the opinion of a recognized and independent ethical commission which the scientific team must obtain. The Authority sends the application for peer review and in the meantime organizes the inspection of the applicant's premises and equipment. The application, the opinion of the ethics committee, the expert evaluations of the application, and the report on the inspection of the conditions for performing research are submitted to the Licensing Committee, which decides whether to grant the license and, if necessary, accomplishes it with additional conditions (Lawford, 2020). Performing germline manipulations without a license or without complying with its conditions is a criminal deed, with penalties ranging from fines to imprisonment of up to two years. Emphasizing the objectives of purely fundamental research, the Authority has been issuing licenses for editing human embryos with CRISPR technology since 2016. Research licensed in this way also require written informed consent from the donors of gametes or embryos for using the donor material in such activities. Public funding of such research is possible in the UK and is in practice. As far as one may see, this order of interaction ensures the controlled research, but without excesses like the Chinese case.

In turn, it is China's experience that makes it possible to understand which option of organizing control faltered and how the public authorities reacted to it. Before China announced the birth of two girls whose DNA had been artificially altered, genetic editing in this country was regulated by the 2003 Ethical Guidelines for Human Embryonic Cell Research. Article 6 of this document prohibited both research on human embryos 14 days after fertilization and any genetic manipulations of human gametes, zygotes, and embryos for reproductive purposes. Manipulations for research purposes required ethical committee approval from any of the authorized medical institutions. In practice, He Jiankui obtained such approval from a private medical company that is known for controlling about 80 % of all private hospitals in the PRC and also for being involved in a lot of rows revealing its commitment to a purely "commercial ethos". This made it abundantly clear that relying on ethical principles alone in an area as sensitive as genetic editing is hardly a brilliant idea.

To be fair, this conclusion was supported by the PRC's central representative body. In 2020, the National People's Congress included in the Civil Code provisions detailing the constitutional right to dignity and regulating biomedical (including genetic) research. According to Article 1008, any clinical trial in this field requires ethical approval and informed consent of affected subjects in disclosing the purpose, objectives and potential risks of such a trial. Article 1009 states that "any medical research activity involving human genes and human embryos shall be conducted in accordance with relevant laws, administrative

regulations and national regulation, shall not harm individuals, and shall not violate ethical morality and public interests"[25].

Naturally, these changes alone could not block options such as those implemented by He Jiankui. However, the matter did not end with them.

At the same time, a draft amendment to the Criminal Code was developed, according to which the specialized elements of crimes related to the illegal practice of human gene editing, cloning of human embryos and a serious threat to the safety of human genetic resources were sanctioned with fines and imprisonment for up to 7 years[26].

However, the key line of defense is in the PRC executive branch. In terms of establishing administrative regulations, there is a delineation of the powers between the Ministry of Science and Technology (regulation of fundamental research) and the National Healthcare Committee (regulation of clinical trials), while the PRC State Council subsequently adopts relevant acts. In 2019, the regulation on fundamental research was adopted. It stipulates that the collection, storage and use of genetic information is subject to either licensing or administrative registration. The sanctions for violating this requirement are fines of up to 5 million yuan or 10 times the amount of illegal profits (after the amendments to the Criminal Code come into force, there should be sanctions for the crime of seriously jeopardizing the safety of human genetic resources). In the same year, a draft regulation on clinical trials was developed to fundamentally change the approval scheme for clinical trials. The National Healthcare Committee stated that all clinical trials involving innovative biomedical technologies would require administrative approval. The regulations proposed by the Committee would categorize gene editing clinical trials into two levels: (1) high risk and (2) low and medium risk. This said, gene editing technology and related assisted reproductive technologies are categorized as high risk and in the future must be approved by the Committee after considering the scientific and ethical aspects of the project[27]. That is, all clinical trials of innovative biomedical technologies must now undergo a double review: internal, conducted by the medical institution, and external, which is the responsibility of the state administrative bodies. The regulations also stipulate requirements for medical institutions applying to conduct clinical trials and (which seems psychologically significant) sanctions in case of the regulations violation for their heads, not just

25 Civil Code of the People's Republic of China. https://clck.ru/3EBLAd

26 In comparison, the French Penal Code, which considers eugenic practices and reproductive cloning as crimes against humanity, allows for imprisonment of up to 30 years and fines of up to 7,500,000 euros (Articles 214-1 and 214-2).

27 Low and medium risk clinical trials will require administrative approval from a provincial Healthcare Department.

the head of the scientific group, as was the case with He Jiankui. In addition, the PRC is discussing plans to establish a National Ethical Review Committee for Science and Technology, specifically to oversee research that raises significant ethical controversy, such as projects involving gene editing technology (Song & Joly, 2021).

The cited examples crystallize an approach that combines administrative control with professional ethical review of planned research and its results. Despite the seemingly cumbersome nature of this combination, it is likely (with appropriate rules for the formation of ethics committees) to ensure, on the one hand, the development of science in the strategically important area with competent professionals involved in decision-making, and, on the other hand, a manageable and relatively bias-free development.

This said, it is possible to develop the procedures for harmonizing the conducting and reporting on research not only for the purposes of distributing public funding, but also for private initiatives[28].

It is necessary to add one more delicate point related to the verification of the obtained results (required, among other things, if we keep in mind the possible transition from fundamental research to clinical trials and introduction of inheritable changes in the human genome within reproductive technologies). Namely, this is the fact that at the moment in Russia only one team claims to have sufficiently serious advances. At first glance, legal science may not be concerned with the current situation. However, some costs begin to be felt at this point, although it is not easy to verbalize them. This is related to the difficulty, in the current situation, to get a full picture of the existing achievements and to assess the prospect of further development. How accurate and effective, in fact, is the editing technology? Can specific results be confidently replicated? What exactly are the complexities of editing, what exactly separates us from the point where we no longer fear the emergence of real children with edited DNA? What exactly is the effect of existing investments in this area, and what are the benefits and costs of further funding specific areas of science? The list of these questions could be continued, but we strongly suspect that in the absence of scientific competition or collaboration between several teams (or a thorough reconciliation of results with foreign colleagues), the answers to these questions will remain vague. This does not help to bring this research out of the somewhat marginalized shadow in which it now seems to have fallen.

[28] As WHO notes, regulations governing the funding of private and public research may impose a number of conditions that function as a governance tool. E.g., these may include: conditions on the source of gametes or embryos (especially on payment and consent of their donors); limits on the time embryos can be maintained in vitro; rules on the creation of hybrid embryos; rights of ownership and disposition of gametes and embryos; and rules on intellectual property rights and the sharing of data and materials. See: Human Genome Editing: a Framework for Governance. § 70.

At the same time, the problem of information exchange raises two other important issues when we try to understand how governance should be structured. One of them is the functioning of the information base on genetic corrections and research in terms of human genome editing[29]. Judging by the website of the Center for High-Precision Editing and Genetic Technologies for Biomedicine[30], there is an impressive record, but still the information is far from complete. The problem of inaccessibility of detailed information on trials is characteristic not only of the genetic research in question, but also of "classical" pharmaceuticals – and the solutions offered by the current regulation seem to be far from ideal[31].

The second related issue is the patentability of the fundamental research results. The literature has already criticized too rigid approaches to (non-)granting patent legal protection to the results of intellectual activity in the field of human embryo genome editing[32]. We believe it is really necessary to find out if this is a possible growth point not just for the existing teams, but for a larger-scale stimulation of scientific research, but in a slightly different aspect. In particular, researchers discuss such well-known ways of managing scientific results as eligibility for publicly funded inventions, government licenses, thematic restrictions, and others. All of them are provided for cases where the government either has an interest of using the technology on its own behalf within certain boundaries, or compels the patent owner to allow another person to use it as the government sees fit (Scheinerman & Sherkow, 2021).

From the above, it is clear that managing the field of genetic editing requires complex solutions, where expectations on some questions clearly influence answers on others.

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29 See: Order of the Russian Government No. 479 of 22.04.2019. (2019). Garant.ru. https://clck.ru/3DruV4

30 Center for High-Precision Editing and Genetic Technologies for Biomedicine. https://clck.ru/3DruWd

31 E.g., there is an open register of clinical trials of medicinal products in the Russian Federation (https://clck.ru/3DruYb), but its content does not allow determining how the trial was conducted, how it ended, etc. Moreover, the Federal Law of April 12, 2010 No. 61-FZ "On circulation of medicines" (part 18, 21 of Article 18) implements the so-called institution of "data exclusivity". Given the established judicial practice (see, e.g.: Definition of the Supreme Court of the Russian Federation of 26. 05.05.2016 No. 305-ES16-2399 in case No. A40-188378/14), the said Law encourages pharmaceutical companies to keep secret the results and details of even successfully conducted clinical trials for at least the period of data exclusivity (up to six years from the date of the drug registration based on the conducted trials). At the same time, given the dynamic development of science and the significance of the trial results both for scientific teams and, ultimately, for society, it can be stated for specific patients that withholding such information and protecting it under the trade secret regime (i) is contrary to the public interest, (ii) may hinder the development of science, (iii) does not allow bona fide companies who publish trial data to enjoy protection under the exclusivity period, and (iv) it is not clear what benefits the state, and in particular, the public healthcare system, can derive from this incentive.

32 See: (Borodin & Kryukova, 2021). More moderate positions in science are also presented. See: (Panagopoulos & Sideri, 2021).

Conclusion

Inheritable human genome editing is a technology that already exists in one way or another. The material part, if we may say so, has already been created for this purpose. Research in this direction is being conducted in Russia, and, importantly, not only in Russia. It is known that managing the development and application of technology is always a process. In this case, the regulation of genetic editing and related practices can be compared to a living organism that has already been brought into the world, at least to be developed in the future.

The situation acquires additional interest due to the fact that in this case almost any advancement in the legal field demands competent discussion with the main stakeholders, which should obviously be built on an iterative principle. Even principle bases and starting points should be checked with the participants of what is going on. This is especially true for the further, more detailed mechanism of interaction between public authorities, representatives of legal and ethical sciences, medical organizations that perform key research functions in the field of editing, patients (patient organizations), etc. The creation and preservation of the discussion horizon allow, on the one hand, to moderate the excitement of discoverers, and on the other hand, not to cold-stack the situation up to the point of complete inaction.

We believe that this situation requires special platforms for interdisciplinary discussion of what regulatory and managerial steps should be taken in Russia to develop the technology; here we tried to present several proposals on this issue.

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Authors' contributions

The authors have contributed equally into the concept and methodology elaboration, validation, formal analysis, research, selection of sources, text writing and editing, project guidance and management.

Conflict of interests

The authors declare no conflict of interests.

Financial disclosure

The research had no sponsorship.

Thematic rubrics

OECD: 5.05 / Law
PASJC: 3308 / Law
WoS: OM / Law

Article history

Date of receipt – June 2, 2024
Date of approval – June 18, 2024
Date of acceptance – September 25, 2024
Date of online placement – September 30, 2024

Научная статья
УДК 34:004:342.721:612.6
EDN: https://elibrary.ru/tklbsa
DOI: https://doi.org/10.21202/jdtl.2024.27

Редактирование генома человека: управление технологическими рисками правовыми средствами

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Ключевые слова

генетические технологии,
генетическое редактирование,
геном человека,
законодательство,
право,
репродуктивные технологии,
рискориентированный подход,
технологический риск,
цифровые технологии,
юридическая ответственность

Аннотация

Цель: определить теоретические подходы к правовому регулированию репрогенетического редактирования с учетом рискориентированного подхода и практики регулирования такого рода прорывных технологий в различных юрисдикциях, а также наметить дальнейшие нормативные и управленческие шаги, которые должны быть предприняты для развития технологии.

Методы: общенаучные методы анализа и синтеза, классификация, системный и функциональный подходы; частнонаучные методы – формально-юридический, сравнительно-правовой, историко-правовой.

Результаты: проведенное исследование показывает возможные варианты подходов к регулированию генетического редактирования в репродуктивных целях. Рассмотренные варианты оценены с точки зрения рискориентированного подхода, определены условия и особенности применения различных регуляторных механизмов, а также дана оценка текущему отечественному регулированию в этой сфере. По итогам анализа возможно заключить, что запрет или существенное ограничение развивающейся технологии репрогенетического редактирования не имеет под собой неопровержимых оснований, более того, может привести скорее к обратным результатам, нежели те, которые декларируются сторонниками такого подхода. В этой связи необходимо развивать дискуссию в конструктивном итеративном ключе, вовлекая в нее всех стейкхолдеров, в том числе научное сообщество.

✉ Контактное лицо

Научная новизна: обобщение и концептуальное осмысление опыта правового регулирования репрогенетических технологий на международном уровне, в рамках различных юрисдикций, а также анализ естественно-научных доводов в контексте оценки эффективности внедряемого регулирования позволяют не только системно рассмотреть существующие и гипотетически возможные риски развития и использования генетических технологий, но дают возможность использовать рискориентированный подход к анализу проблем правового регулирования технологий редактирования генома человека. Это позволяет сделать следующий шаг в осмыслении феномена генетического редактирования.

Практическая значимость: результаты настоящего исследования могут быть использованы для целей выстраивания дальнейшего конструктивного диалога по поводу применения правовых механизмов к вопросам редактирования генома человека. Исследование также возможно рассматривать в качестве основы для использования итеративного подхода в рамках дальнейшей дискуссии.

Для цитирования

Троицкая, А. А., Шарловский, К. А. (2024). Редактирование генома человека: управление технологическими рисками правовыми средствами. *Journal of Digital Technologies and Law*, *2*(3), 521–543. https://doi.org/10.21202/jdtl.2024.27

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Вклад авторов

Авторы внесли равный вклад в разработку концепции, методологии, валидацию, формальный анализ, проведение исследования, подбор источников, написание и редактирование текста, руководство и управление проектом.

Конфликт интересов

Авторы сообщают об отсутствии конфликта интересов.

Финансирование

Исследование не имело спонсорской поддержки.

Тематические рубрики

Рубрика OECD: 5.05 / Law
Рубрика ASJC: 3308 / Law
Рубрика WoS: OM / Law
Рубрика ГРНТИ: 10.07.45 / Право и научно-технический прогресс
Специальность ВАК: 5.1.1 / Теоретико-исторические правовые науки

История статьи

Дата поступления – 2 июня 2024 г.
Дата одобрения после рецензирования – 18 июня 2024 г.
Дата принятия к опубликованию – 25 сентября 2024 г.
Дата онлайн-размещения – 30 сентября 2024 г.