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Constitutional and Legal Framework for the Use of CRISPR-Cas9 Technologies: China's Experience

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Abstract

Objective To examine the evolution of the legal regulation of basic and preclinical human genome editing research in the People's Republic of China from 1990 to 2025. Human genome editing is one of the most legally and ethically controversial areas of modern biomedicine. The experience of legal regulation in the field of CRISPR/Cas9 technologies in the People's Republic of China (PRC) is analyzed. Here, the evolution of these technologies has been accompanied by the formation of a national regulatory framework aimed at ensuring a balance between scientific progress and bioethical restrictions.

Methodology General and specific scientific methods were used, including legal analysis and synthesis, along with the methods of systems, logical-structural and historical-legal analysis.

Results The activities of China's state bodies (National Health Commission (NHC), Ministry of Science and Technology (MoST), National Ethics Committee for Science and Technology (NECST) in the field of public health policy were analyzed. These bodies ensure the development and application of genome editing technologies, the ethical management of scientific and technological research in this area, including human genome editing. The evolution of China's national legislation in the field of application of human genome editing technologies was analyzed, including laws, regulations, ethical standards, procedural protocols governing research on genetic modifications using human gametes, embryos and germ cells. The trend toward tightening the legal regime for genome editing in the period from 2018 to the present was noted, which was caused by both the rapid development of technologies (CRISPR-Cas9, base editing) and the He Jiankui case. The new version of the "Measures for Ethical Review of Life Sciences and Medical Research Involving Human Beings" (2023), "Trial Measures for Scientific and Technological Ethics Review" (2023), "Ethical Guidelines for Human Genome Editing" (2024) were analyzed. These documents reflect strengthening requirements for the content of ethical review based on respect for human rights. Legislative innovations that provide for criminal liabili-

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ty for illegal implantation of genetic engineering, embryo cloning, illegal collection and smuggling of human genetic resources were outlined.
Conclusions Research in the field of human gene editing should be based on understanding the ethical and legal aspects of clinical practice and the development of adequate mechanisms for regulatory control. The rapid development of genetic engineering technologies determines the need for scientific understanding of the legal regulation of relations arising in connection with the use of CRISPR-Cas9 technologies, primarily from the standpoint of respect for human rights, the limits of intervention in the genome, and determining the legal status of genomic and genetic information. In accordance with the principle of using scientific progress for the benefit of society, a balanced assessment of the interaction of innovations and risks in human genome editing is extremely important.

Keywords: CRISPR-Cas9 technologies, human genome editing, genetic materials, biomedical sector, People's Republic of China

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Конституционно-правовая база использования технологий CRISPR-Cas9: опыт Китая

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Аннотация

Цель: Целью данной статьи является рассмотрение эволюции правового регулирования фундаментальных и доклинических исследований по редактированию генома человека в Китайской Народной Республике с 1990 по 2025 г. Редактирование генома человека является одним из наиболее сложных в правовом и этическом отношении направлений современной биомедицины. В статье представлен анализ опыта правового регулирования использования технологий

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CRISPR/Cas9 в Китайской Народной Республике (КНР), где эти технологии прошли определенный этап эволюционного развития, сопровождавшийся формированием национальной нормативной правовой базы, направленной на обеспечение баланса между научным прогрессом и биоэтическими ограничениями.

Методология: В исследовании использованы общенаучные и специальные когнитивные методы, включающие правовой анализ и синтез, системный, сравнительно-правовой, логический и историко-правовой методы.

Результаты: В исследовании проанализирована деятельность ключевых государственных органов (Национальная комиссия по здравоохранению (NHC), Министерство науки и технологий (MoST), Национальный этический комитет по науке и технологиям (NECST)), обеспечивающих системный подход к реализации государственной политики в области здравоохранения, разработке и применению технологий редактирования генома, развитию науки в этой области, этическому управлению научными и технологическими исследованиями, включая редактирование генома человека. В работе представлен детальный анализ эволюции национального законодательства Китайской Народной Республики в области применения технологий редактирования генома человека: законов, нормативных актов, этических стандартов, процессуальных протоколов, регламентирующих исследования по генетическим модификациям с использованием человеческих гамет, эмбрионов и половых клеток. Авторами выявлена тенденция ужесточения правового режима редактирования генома в период с 2018 г. по настоящее время, что вызвано как стремительным развитием технологий (CRISPR-Cas9), так и делом Хэ Цзянькуя. Анализ таких документов, как «Меры этической экспертизы исследований в области естественных наук и медицины с участием людей» (2023), «Пробные меры этической экспертизы научной и технологической деятельности» (2023), «Этические принципы редактирования генома человека» (2024), подчеркивает важность требований к содержанию этической экспертизы, основанной на соблюдении прав человека. В статье анализируются законодательные нововведения, предусматривающие уголовную ответственность за незаконную имплантацию генно-инженерных технологий, клонирование эмбрионов, незаконный сбор и контрабанду генетических ресурсов человека.

Выводы: Исследования в области редактирования генов человека должны основываться на понимании этических и правовых аспектов клинической практики и разработке адекватных механизмов нормативного контроля. Стремительное развитие генно-инженерных технологий обусловливает необходимость научного осмысления правового регулирования отношений, возникающих в связи с использованием технологий CRISPR-Cas9, прежде всего с позиций соблюдения прав человека, пределов вмешательства в геном и определения правового статуса геномной и генетической информации. В соответствии с целью исполь-

зования научного прогресса на благо общества чрезвычайно важна сбалансированная оценка взаимодействия инноваций и рисков при редактировании генома человека.

Ключевые слова: технологии CRISPR-Cas9, редактирование генома человека, генетические материалы, биомедицинский сектор, Китайская Народная Республика

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Introduction

The advancement of human genome editing technologies has led to significant changes in the global biomedical sector. Modern gene editing methods continue to develop intensively, resulting in the emergence of numerous innovations. At present, humanity has entered the epicenter of an anthropological revolution, which raises concern among researchers regarding the necessity of legal regulation in the sphere of genome editing technologies from the standpoint of human right protection (Vasiliev et al., 2022).

Numerous genetic engineering technologies have become widespread to date, including the use of zinc finger nucleases (ZFNs), nucleases with transcription activator-like effectors (TALENs), and systems based on clustered regularly interspaced short palindromic repeats (CRISPR). This field is currently undergoing a phase of rapid development and adoption, with CRISPR-related technologies predominating. According to Russian scholars, the scope of CRISPR/Cas9 and related GRGs technologies continues to expand exponentially. These innovations are currently used to create genetically modified microorganisms, plants and animals. In addition, they significantly extend the capabilities of experimental methods for studying the genetic foundations of life and form the basis for developing revolutionary approaches to the treatment and prevention of previously incurable diseases (Karagyaur et al., 2019). CRISPR/Cas technology has become an indispensable tool in both fundamental and applied research (Liu et al., 2022; Bharathkumar et al., 2022).

Human genome editing can be distinguished into two main types, namely (1) somatic genome editing and (2) germline genome editing, with each serving the key functions of therapeutic intervention, disease prevention, and genetic enhancement (Huo, 2013). Germline genome editing entails modifications to the DNA of reproductive cells, zygotes, or embryos. Such alterations are heritable, with potential implications for the human gene pool and broader biosafety concerns. Despite significant scientific progress and technological breakthroughs,

this field remains fraught with legal, safety, and ethical challenges. Russian constitutional scholars draw attention to the need of achieving a balance between the rapid introduction of telemedicine technologies and the prevention of unjustified restrictions (deprivations) of individual rights, including the right for human dignity (Kostenkov, Komarova, 2024), as well as the importance of observing ethical standards (Siluyanova, 2021), the transformation of the relationship between private and public interests (Romanovskiy, 2025), the need for legal consolidation of the genomic and the genetic information legal status (Kubyshkin et al., 2025).

The research in the field of human gene editing should be grounded upon a clear understanding of the ethical and legal aspects of clinical practice and the development of adequate mechanisms of regulatory control. A responsible approach to gene editing research and application is imperative, with ethical considerations taking precedence to ensure that technological advancements would yield beneficial outcomes (Chen et al., 2018). Additionally, careful differentiation among various ethical dilemmas is crucial to facilitate the sustainable development and responsible implementation of these technologies. In alignment with the objective of harnessing scientific progress for societal benefit, a balanced evaluation of the interplay between innovation and risk in human genome editing is essential. This entails weighing technical risks against clinical benefits while emphasizing proactive risk mitigation strategies (Garden, Winickoff, 2019). In this regard, the experience of legal regulation of the use of CRISPR/Cas9 technologies in the People's Republic of China (PRC) might be of interest.

In the People's Republic of China, the development of human gene editing has been accompanied by creation of a regulatory framework aimed at balancing scientific progress and bioethical constraints. The constitutional framework provides the foundational basis for regulating biomedical research and human genome editing through several key provisions. Article 21 of the Constitution of the People's Republic of China (1982) declares that "the State develops medical and health services, promotes modern medicine and traditional Chinese medicine, encourages and supports the setting up of various medical and health facilities by the rural economic collectives, state enterprises and institutions and neighborhood organizations, and promotes health and sanitation activities of a mass character, all for the protection of the people's health. The State develops physical culture and promotes mass sports activities to improve the people's physical fitness"[1]. This constitutional mandate serves as an overarching legal foundation for state involvement in regulating medical research and biotechnology.

The constitutional framework functions within a people-centered paradigm as characterized by Chinese scholars, wherein public health and safety are of paramount importance along with the facilitation of technological progress (Xue, Shang, 2022). This constitutional doctrine serves as the foundation for China's precautionary stance on biotechnology governance, asserting that scientific and technological uncertainties should not preclude the implementation of preventive

[1] *Ministry of Science and Technology (MoST) of the People's Republic of China*. Available at: https://en.most.gov.cn/

measures to mitigate potential harm (Cao, 2021). In addition, the integration of national security considerations into the Constitution is becoming increasingly prominent. The Constitution of the People's Republic of China (1982) includes biosafety and biosecurity as the components of national security. The constitutional recognition of biosafety as a matter of national security establishes a legal foundation for comprehensive regulatory governance over research involving human genome editing (Cao, 2021).

Methods

In this research, we used general and specific scientific methods of cognition. The general scientific methods involved analysis and synthesis when working with legal acts, academic literature, and documents. The analytical method was used to study the content of genome editing technologies in the scientific legal doctrine, to formulate tasks that require legal regulation in the domestic practice of using genomic technologies. The synthesis method was used to identify the main trends in the development of Chinese legislation in the field of genome editing. The systems approach was used to establish the structure of government agencies and their interaction in the implementation of state health policy on the development and editing of human genome. Logical and structural methods were instrumental in identifying specific features in the implementation of the powers of Chinese government agencies in the topic under study. The historical and legal research method allowed us to identify the main stages in the formation of China's national legislation from the 1990s up to the present.

Results

Legal regulation of the activities of state bodies in the field of human genome editing in China

The governance of human genome editing is implemented through a multi-ministerial coordination system including several governmental authorities. The National Health Commission (NHC)[2] and the Ministry of Science and Technology (MoST)[3] play key, although different, roles in regulating both human genome editing policy and health and science policy.

The MoST is the main governmental authority which is responsible for the research policy, technological innovation, and ethical governance in the field of genome editing. It is responsible for the development of scientific and ethical guidelines for genome editing research, the implementation of regulatory standards, and the supervision of human genetic resource usage during scientific research. The MoST formulates and implements a legal framework governing research ethics, facilitates inter-ministerial coordination in the field of genome editing

[2] The State Council has issued the Decision of the State Council on Amending and Repealing Part of the Administrative Regulations (State Order No. 777), which transferred the management authority of human genetic resources from the Ministry of Science and Technology (MoST) to the National Health Commission (NHC), among other adjustments. The change took effect on May 1, 2024.
Decision of the State Council on Amending and Repealing Certain Administrative Regulations. (2024). Available at: https://www.gov.cn/zhengce/content/202403/content_6939590.htm *(In Chinese).*

[3] *National Ethics Committee for Science and Technology (NECST).* Available at: https://www.nsfc.gov.cn/csc/20340/20289/64938/index.html

and biotechnology. It grants administrative approvals for research with human genetic material and ensuring compliance with prescribed protocols. The MoST is responsible for the national ethical standards and implementation of the institutional research procedures, ensuring the inter-institutional coordination, issuing administrative licenses for research with human genetic material, monitoring compliance with prescribed procedural guidelines.

At the international level, the MoST promotes scientific cooperation within defined regulatory boundaries while controlling foreign access to human genetic resources in China to ensure national biosafety and research sovereignty. The MoST acts as the central regulatory body, balancing scientific progress with ethical and legal safeguards in the field of genome editing, while involving both domestic stakeholders and global partners in a structured governance system.

In March 2023, the National Legislative Assembly announced plans to transfer control of human genetic material to the National Health Commission (NHC). It meant the shift of policy towards public health in the management of human genetic resources. The MoST terminated the activity of one of its institutions, the Genetic Resources Authority, which had functioned for 25 years, and transferred all powers in the field of human genetic resources to the National Health Commission (NHC)[4].

The NHC has become the main governmental authority that is responsible for developing and implementing health legislation and policies to ensure compliance with national and international biomedical standards. It oversees health-care facilities and clinical practice, providing rigorous oversight to prevent ethical and safety violations. In addition, the NHC plays a key role in the management of public health and disease control, reinforcing its central position in China's healthcare system. One of its key functions is to administer the ethical review processes for biomedical research involving human participants, in particular, in genome editing and clinical trials. By upholding safety and ethical standards, the NHC ensures that the experimental treatments meet the medical and bioethical standards, protecting patient and public safety. Beyond regulatory functions, the NHC coordinates national healthcare services, including mental health programs, pediatric care, and public hospital reforms, striving for equitable access to medical services. It also implements public health campaigns aimed at improving population-wide well-being, with a focus on mental health awareness and child healthcare development.

Being China's leading health regulatory authority, the NHC balances domestic healthcare governance with global health engagement, ensuring that advancements in genome editing and biomedicine proceed within the framework of safety, ethics, and public accountability through transparent regulatory processes. Its multifaceted role underscores its importance in both national health policy and international biomedical discourse.

In 2019, China adopted the "Plan for the Establishment of the National Ethics Committee for Science and Technology". In 2021,

[4] *Central Science and Technology Commission (CSTC)*. Available at: https://baike.baidu.com/item/%E4%B8%AD%E5%A4%AE%E7%A7%91%E6%8A%80%E5%A7%94%E5%91%98%E4%BC%9A/62748355. *(In Chinese)*.

the MoST officially established the National Ethics Committee for Science and Technology (NECST)[5], which is responsible for three areas – artificial intelligence, life sciences, and medicine (Sun, 2025). It serves as the central authority for ethical governance of science and technology research, including human genome editing, artificial intelligence, and other emerging fields. The National Science and Technology Ethics Committee (NSTEC) is the cornerstone of China's system of ethical governance of new technologies, including human genome editing. The NSTEC functions as an integral component of China's centralized science and technology governance system. It operates under the MoST supervision and reports to higher authorities, such as the Central Science and Technology Commission (CSTC)[6]. This structure reflects a strategic approach to aligning scientific innovation with national priorities and societal responsibility, ensuring that technological progress adheres to ethical and regulatory standards. It fulfills the main function of ensuring scientific progress within an ethical framework that protects the public welfare. The NSTEC drafts ethical principles for high-risk research areas, such as genome editing and artificial intelligence; supervises the activity of institutional ethical review boards, supports researchers and institutions in conducting comprehensive ethical risk assessments; provides permanent supervision over research during its lifecycle, which includes handling complaints, conducting audits, and coordinating with governmental authorities, particularly in areas where research involves national security and state secrets.

Evolution of China's national legislation on the application of human genome editing technologies

The legal framework of China consists of multiple regulations. The laws are promulgated by the National People's Congress of the People's Republic of China and are binding upon the responsible governmental authorities[7]. The regulations are formulated through inter-ministerial collaboration, ratified by the State Council of the People's Republic of China, and are legally valid[8]. The ministerial guidelines control the institutional and research conduct and may be issued as ethical principles or administrative measures. According to Articles 71 and 82 of the Legislation Law of the People's Republic of China (2000)[9], administrative measures are exerted over specific research activities or institutional operations. These measures are promulgated by ministerial or governmental authorities that are subordinated to the State Council of the People's Republic of China and constitute a formal source of legal norms within the Chinese legal system. The ethical guidelines and principles are intended to manage biotechnological research in accordance with

[5] *National People's Congress of the People's Republic of China*. Available at: http://www.china.org.cn/
[6] *State Council of the People's Republic of China*. Available at: https://english.www.gov.cn/
[7] Legislation Law of the People's Republic of China (2020). Available at: https://www.cecc.gov/resources/legal-provisions/legislation-law-chinese-and-english-text
[8] *National Health Committee, the Ministry of Science and Technology, and the Chinese Association for Science and Technology: Response to Gene-edited Babies*. Available at: https://www.edu.cn/ke_yan_yu_fa_zhan/zui_jin_geng_xin/201811/t20181128_1634933.shtml. *(In Chinese)*.
[9] *Measures on the Management of the Safety of Genetic Engineering. (1993)*. Available at: https://www.gov.cn/zhengce/1993-12/24/content_5711088.htm. *(In Chinese)*.

social morality and public order. The technical regulations or standards are implemented to guarantee the safety and effectiveness of specific technologies; they have legal force when being referred to in laws, regulations, or administrative measures (Huo, 2013).

Since the 1990s, China's governmental authorities have enacted an extensive legislative and policy framework to regulate the biomedicine and bioscience sector. It comprises laws, regulations, ethical standards, and procedural protocols governing research on genetic modifications involving human gametes, embryos, and germline cells. This framework is applicable to both fundamental and preclinical research, as well as to potential clinical trials (Ishii, 2015).

The period from 2001 to 2018 was a key milestone in the development of China's regulatory framework for human genome editing. During that time, Chinese legislation actively responded to the rapid development of biotechnology, while attempting to strike a balance between scientific progress and ethical and legal constraints.

The period from 2018 to 2025 was marked by a dramatic tightening of the legal regulation of genome editing. This was caused both by the rapid development of technologies (CRISPR-Cas9, base editing) and the He Jiankui case. Prior to this incident, China had been a global leader in the field of genome editing of both human and nonhuman primates. Some scholars consider that genome modifications in human or primate somatic cells raise fewer ethical concerns compared to interventions in human germline cells or heritable genetic editing (Zhang et al., 2023). Today, human gene editing of somatic cells is extensively used in fundamental, preclinical and clinical trials, particularly in therapeutic interventions for malignant, hematologic, endocrine, and immune diseases. The research involving human germline genome editing has caused significant controversy and ethical debate. In 2015, a team led by Huang Junjiu from Sun Yat-sen University edited human triple pronucleus embryos in the laboratory for the first time (Liang et al., 2015). Following Huang's experiment, a leading Chinese bioethicist, Professor Qiu Renzong expressed his viewpoint that human somatic and germline editing should be permitted while human heritable genome editing and genetic enhancement should be prohibited (Zhang et al., 2023).

In 2018, the controversial He Jiankui incident occurred. This researcher genetically modified the CCR5 gene to prevent the inheritance of HIV from an infected father to his children. He was widely condemned domestically and globally. In an official statement, the MoST and the NHC stressed that genetically modifying a human embryo for reproductive purposes is explicitly prohibited in China. He Jiankui received widespread condemnation for severely violating ethical morality, scientific integrity, and relevant regulations[10]. In December 2019, He was ultimately convicted of illegal medical practices and sentenced to three years in prison. He violated Article 336 of the Criminal Law of the People's Republic of China, which prohibits unlicensed medical activities (Greely, 2019). China has also realized the importance of ethical governance in science and has accelerated legislation in this area. Subsequently, the amendments of the Civil Code

[10] *Regulations on the Safety Management for Biotechnology Research and Development*. (2017). Available at: https://www.most.gov.cn/xxgk/xinxifenlei/fdzdgknr/fgzc/gfxwj/gfxwj2017/201707/t20170725_134231.html. *(In Chinese)*.

and the Criminal Law of the People's Republic of China prohibit the implantation of genetically edited human embryos into humans or animals. Overall, the Chinese legislators responded quickly to the He Jiankui incident, by issuing new laws and regulations, or revising the existing ones. Violations related to human genome editing were often included in low-level administrative regulations, and the He Jiankui incident promoted the inclusion of such violations in laws (Xiaofu, 2021).

China's regulatory legal acts in the sphere of human genome editing

In China, human genome editing is regulated by four main groups of regulations. The first group is aimed at ensuring biosafety. In the early 1990s, China did not have specialized legislation in the field of genetic research, although general principles of regulation of medical and biological activities were enshrined in a number of administrative regulations (Huo, 2013). As early as 1993, China issued the "Measures on the Management of the Safety of Genetic Engineering" (1993)[11]. These measures cover such aspects as approval, supervision, safety assessment, and accident management of genetic engineering projects, aiming to prevent potential risks that genetic engineering may pose to the environment and human health. These regulations focus more on biosafety rather than ethical review (Cao, 2021).

In 2017, the MoST issued the "Regulations on the Safety Management for Biotechnology Research and Development"[12]. These regulations control biotechnology research and development activities, raise awareness of the security responsibilities of individuals, legal entities and other organizations engaged in biotechnology research and development, prevent direct or indirect threats to biological security, promote and ensure the healthy and orderly development of biotechnology research and development activities, and effectively maintain biological security.

In 2020, the Biosecurity Law of the People's Republic of China[13] was promulgated (entered into force on April 15, 2021). This law represents the cornerstone of China's modern regulatory framework for biomedical research. This fundamental law defines biosecurity as "the status that means that the State effectively prevents and responds to threats from dangerous biological factors and related factors, biotechnology can develop stably and healthily, people's lives and health and the ecosystem are relatively free from danger and threats, and the biological field has the ability to maintain national security and sustainable development" (Article 2). Article 3 of the Biosecurity Law of the People's Republic of China establishes that "biosecurity is an important part of national security" and must be maintained through "principles of people first, risk prevention, classified management, and coordination and cooperation". This provision creates the legal foundation for treating human genome editing research as a matter of national security requiring comprehensive state oversight (Xiao-

[11] *Biosecurity Law of the People's Republic of China. (2020).* Available at: https://law.pkulaw.com/chinalaw/736cc84db120a6d5bdfb.html. *(In Chinese).*

[12] *Interim Measures for the Management of Human Genetic Resources. (1998).* Available at: https://chinareal.nankai.edu.cn/info/1037/3642.htm. *(In Chinese).*

[13] *Measures for the Administration of Human Assisted Reproductive Technology. (2001).* Available at: http://big5.www.gov.cn/gate/big5/www.gov.cn/gongbao/content/2002/content_61906.htm. *(In Chinese).*

fu, 2021). Chapter VI "Human Genetic Resources and Biological Resources Security" emphasizes state sovereignty, biosafety and ethical governance, restricting foreign access and encouraging controlled international cooperation. The laws stipulate strict resource authorization processes, specifically for sensitive activities such as cross-border transfers or research involving foreign organizations. Mandatory participation of Chinese institutions in international projects ensures equitable benefit sharing and protects national interests. Thus, individuals engaged in biological research prohibited by law are subject to clear penalties, such as fines and revocation of professional certificates. At the same time, biodiversity protection measures address environmental risks associated with invasive species, reflecting a holistic approach to balancing scientific progress and regulatory control. Together, these provisions underscore China's strategy to use genetic and biological resources as strategic assets under centralized management.

The second group of regulations is related to human genetic resources, assisted reproductive technologies, and research on human embryonic stem cells. As early as 1997, geneticist Tan Jiazhen wrote a letter to the central government calling for the protection of human genetic resources in China (Zou et al., 2025). The MoST has formulated the "Interim Measures for the Management of Human Genetic Resources" (1998)[14]. According to these measures, the MoST established the Management Office of Chinese Human Genetic Resources in 1999, which is mainly responsible for regulating and managing the collection, trade, export, and other matters related to Chinese human genetic resources.

In 2001, the "Management Measures for Human Assisted Reproductive Technology" were promulgated[15]. This document governs the use of assisted reproductive technology (ART) by setting strict requirements for medical facilities. ART procedures are performed only in licensed centers with mandatory informed consent of patients and the required level of confidentiality. Special attention is paid to the prohibition of commercialization of biomaterials, gender selection, and surrogacy. Compliance controls include periodic inspections and technical monitoring, and violations are subject to administrative or criminal liability. Medical institutions must establish medical ethics committees and provide informed consent when assisted reproductive technologies are implemented.

In 2003, the "Ethical Guidelines for Research on Human Embryonic Stem Cells" were issued, emphasizing the 14-day rule for embryonic research, explicitly prohibiting human cloning research, and stipulating those institutions involving human embryonic stem cell research should establish ethics committees[16].

In 2016, the MoST submitted a draft of the "Regulations on the Management of Human Genetic Resources" to the State

[14] *Ethical Guidelines for Research on Human Embryonic Stem Cells.* (2003). Available at: https://www.scrcnet.org/download/eccr_31.pdf. *(In Chinese).*

[15] *Regulations on the Management of Human Genetic Resources.* (2019). Available at: https://www.gov.cn/zhengce/content/2019-06/10/content_5398829.htm. *(In Chinese).*

[16] *Implementation Rules for the Regulations on Human Genetic Resources* (2023). Available at: https://www.most.gov.cn/xxgk/xinxifenlei/fdzdgknr/fgzc/bmgz/202306/t20230601_186416.html. *(In Chinese).*

Council of the People's Republic of China. In 2019, the "Regulations on the Management of Human Genetic Resources" were promulgated, which regulate the use of Chinese human genetic resources by foreign and domestic institutions and individuals, to ensure that these activities do not endanger China's public health and safety, and include administrative penalties for violations[17]. They require international collaborations to adhere to human genetic resources guidelines. Certain materials, such as whole blood, tissue biopsies, and genetic sequencing data, are subject to increased scrutiny. Licensing and compliance vary based on the activity and nature of collaboration projects. The regulations mandate a rigorous pre-entry application and licensing process, ongoing reporting, audits, and internal controls to ensure compliance.

After the promulgation of the Regulations, the MoST extensively solicited expert opinions, launched the formulation of relevant supporting implementation rules, and issued the detailed "Implementation Rules for the Regulations on Human Genetic Resources"[18]. In 2023, further clarifications were provided, resulting in a reduction of strict requirements and an optimization of the review process for human genetic resources.

The third set of regulations aims to regulate the ethical review of biomedical research and clinical trials, which China has been actively promoting over the past two decades. First, as China continues to invest in biomedical technologies, establishing and improving ethical review systems has become increasingly important. Second, the development of medicine with international standards has promoted the standardization of medical ethics reviews.

In 2007, the "Notification on Ethical Review of Biomedical Research Involving Human Subjects"[19] and, in 2016, the "Measures for the Ethical Review of Biomedical Research Involving Humans"[20] were issued. These measures supplement the previous regulations to ensure that research in sensitive areas, such as human germline genome editing, is not only regulated in terms of biosafety but also should comply with detailed ethical standards. They clarify the scope of application, basic principles, and responsibilities of ethical committees and require that all medical and healthcare institutions establish ethics committees for implementing risk control, privacy protection, etc., to ensure the ethical standard of research. In addition, these regulations clearly stipulate that those institutions and individuals who violate the provisions of these measures and damage the personal property of others will bear civil liability or be held criminally responsible in accordance with the legislation.

Similarly, in 2010, the "Guiding Principles for Ethical Review of Drug Clinical Trial"[21] were enacted in order to ensure the digni-

[17] *Measures for the Ethical Review of Biomedical Research Involving Humans. (2007).* Available at: https://www.nhc.gov.cn/wjw/gfxwj/200703/904f1976ed3d4da49eb56b0edf6e00b2.shtml. *(In Chinese).*

[18] *Measures for the Ethical Review of Biomedical Research Involving Humans. (2016).* Available at: https://www.beijing.gov.cn/gate/big5/www.beijing.gov.cn/zhengce/zhengcefagui/qtwj/201610/t20161021_780889.html. *(In Chinese).*

[19] *Guiding Principles for Ethical Review of Drug Clinical Trial. (2010).* Available at: https://www.nmpa.gov.cn/directory/web/nmpa/xxgk/zhqyj/zhqyjyp/20090805163901480.html. *(In Chinese).*

[20] *Measures for Ethical Review of Life Sciences and Medical Research Involving Human Beings. (2023).* Available at: https://www.gov.cn/zhengce/zhengceku/2023-02/28/content_5743658.htm. *(In Chinese).*

[21] *Trial Measures for Scientific and Technological Ethics Review. (2023).* Available at: https://www.most.gov.cn/xxgk/xinxifenlei/fdzdgknr/fgzc/gfxwj/gfxwj2023/202310/t20231008_188309.html. *(In Chinese).*

ty, safety, rights, and interests of the subjects, to promote the scientific and healthy development of clinical drug research, and to increase public confidence and support for clinical drug research.

In February 2023, four governmental authorities (NHC, Ministry of Education, MoST, and State Administration of Traditional Chinese Medicine) released a revised version of the "Measures for Ethical Review of Life Sciences and Medical Research Involving Human Beings"[22]. At the same time, the regulations promulgated in 2016 have not been superseded and continue to be applied in parallel with the more recently enacted rules. The change in the name of the document from "biomedical" to "life sciences and medicine" demonstrates the expansion of the ethical review approach and its optimization beyond the field of medical research (Cao, 2021). The most crucial part of the entire document is the revision of the rules related to the ethics review committee and ethics review. The new rules not only strengthen the functions of the ethics review committee, but also provide more-detailed regulations on the content of ethics review. In addition, the new rules reflect the "people-oriented" thinking of Confucianism, while the establishment and improvement of informed consent rules reflect the respect for human rights (Gang, Peng, 2023).

On September 7, 2023, the "Trial Measures for Scientific and Technological Ethics Review" were released by the MoST, the Ministry of Education, the Ministry of Industry and Information Technology, the Ministry of Agriculture and Rural Affairs, the NHC, the Chinese Academy of Sciences, the Chinese Academy of Social Sciences, the Chinese Academy of Engineering, the China Association for Science and Technology, and the Science and Technology Commission of the Central Military Commission[23]. The "Trial Measures" took effect on December 1, 2023, mandating ethics reviews for certain types of research. According to this document, Chinese higher education institutions are required to conduct an ethics review any time they are carrying out certain scientific and technological activities, including those involving human research participants, experiments on animals, and activities involving data and algorithms (e.g., artificial intelligence).

In November 2023, the National Medical Products Administration issued the "Measures for the Supervision and Inspection of Drug Clinical Trial Institutions (for Trial Implementation)", which apply to inspection by drug regulatory authorities of drug clinical trial institutions ("trial institutions") and oversight over the compliance of drug clinical trial activities related to drug registration with relevant laws and regulations[24].

On July 8, 2024, the MoST published a new set of "Ethical Guidelines for Human Genome Editing"[25]. These guidelines outline general and specific requirements for human ge-

[22] United States v. Semrau, 693 F.3d 510, 527 (6th Cir. 2012). Available at: https://www.opn.ca6.uscourts.gov/opinions.pdf/12a0312p-06.pdf

[23] *Определение Судебной коллегии по уголовным делам Верховного Суда Российской Федерации от 2.02.2023 № 74-УД23-1-А5.* Режим доступа: https://legalacts.ru/sud/opredelenie-sudebnoi-kollegii-po-ugolovnym-delam-verkhovnogo-suda-rossiiskoi-federatsii-ot-02022023-n-74-ud23-1-a5/

[24] *Drug Administration Law of the People's Republic of China*. Available at: http://www.npc.gov.cn/zgrdw/englishnpc/Law/2007-12/14/content_1384270.htm

[25] *Law on the Progress of Science and Technology.* (2021). Available at: https://www.most.gov.cn/xxgk/xinxifenlei/fdzdgknr/fgzc/flfg/202201/t20220118_179043.html. *(In Chinese).*

nome editing research. Among the specific requirements, those regarding both basic and preclinical human genome editing research are clearly defined. The document highlights that the use of edited germ cells, fertilized eggs, or human embryos for pregnancy or reproduction is strictly prohibited. Clinical research involving genome editing of somatic cells, i.e., cells in the body other than sperm and egg cells, should be aimed at preventing or treating diseases and should be carried out after animal tests or preclinical, in vitro experiments that have offered basic evidence of safety and efficacy. In terms of conducting genome editing of human embryos or fetal somatic cells, it is also necessary to carefully evaluate the risk of potential heritable variations. Particular requirements have been specified for handling leftover samples and the conditions for using somatic cell genome editing strategies at different stages of research, namely, basic research, preclinical research, and clinical research.

The fourth category includes other common laws and regulations related to healthcare, science and technology, as well as criminal and civil laws, e.g., the Drug Administration Law of the People's Republic of China[26], the Law on the Progress of Science and Technology (2021)[27], the Law of the People's Republic of China on Basic Medical and Health Care and the Promotion of Health[28], the "Regulations of the National Natural Science Foundation of China"[29].

The Chapter 1 "General provisions" of the Civil Code of the People's Republic of China states that "this law is formulated in accordance with the Constitution in order to protect the legitimate rights and interests of civil subjects, adjust civil relations, maintain social and economic order, adapt to the development requirements of socialism with Chinese characteristics, and promote the core socialist values" (Article 1)[30].

The Constitution of the People's Republic of China is the fundamental law of the country that has the highest legal effect (Xue, Shang, 2022). This statement shows the legislative basis and legitimacy of the Civil Code, at the same time as showing that civil law reflects the spirit and principles of the Constitution, as well as the refinement and implementation of the provisions of the Constitution of the People's Republic of China on the protection of citizens' fundamental rights. The Constitution of the People's Republic of China clearly stipulates that the State respects and protects human rights (Article 33) and that "the personal dignity of citizens of the People's Republic of China shall not be violated" (Article 38)[31].

The embodiment of the Constitution principles of the People's Republic of China in the Civil Code of the People's Repub-

[26] *Law of the People's Republic of China on Basic Medical and Health Care and the Promotion of Health*. (2021). Available at: http://en.moj.gov.cn/2021-06/26/c_636455.htm

[27] *Regulations of the National Natural Science Foundation of China*. Available at: https://www.nsfc.gov.cn/english/site_1/policy/B3/2017/12-29/41.html

[28] *Civil Code of the People's Republic of China*. (2020). Available at: https://www.gov.cn/xinwen/2020-06/01/content_5516649.htm. *(In Chinese)*.

[29] *Constitution of the People's Republic of China*. (1982). Available at: http://www.npc.gov.cn/zgrdw/npc/zt/qt/gjxfz/2014-12/04/content_1888197.htm

[30] https://www.gov.cn/xinwen/2020-06/01/content_5516649.htm.

[31] Ibid.

lic of China is directly reflected in Article 109 of Chapter 5 "Civil Rights". It states that "the personal freedom and personal dignity of people are protected by law." This means that all civil activities, including human gene editing, must comply with the basic norms of protecting personal dignity and ensure the priority of people. Article 8 states that "civil subjects shall not violate the law or public order and good morals when engaging in civil activities." Together with Article 153 of the Civil Code of the People's Republic of China, it sets the behavioral boundaries for gene editing activities, aiming to make up for the deficiencies of mandatory legal provisions (Zou et al., 2025).

In addition to existing provisions, in cases where human gene editing activities violate public order and good customs, the law will make a negative evaluation of the effectiveness of such behavior and render it illegal. Book 4 "Personality Rights" of the Civil Code of the People's Republic of China is the core regulation for human gene editing activities. Thus, in Chapter 1 "General Provisions", Article 990 clarifies the basic types of specific personal rights and provides extensive protection for personal rights and interests through the general personal rights clause, reserving a space for other personal dignity infringements that may be caused by human gene editing. The system of personal rights claims under Article 995, the system of mental damages for breach of contract under Article 996, and the system of injunctions under Article 997 have important applications in regulating human gene editing activities and damages.

Following the He Jiankui case, in May 2020, the Civil Code of the People's Republic of China added a new article about medical and scientific research activities related to human genomes and embryos (Chapter 2. Right to life, body, and health). Article 1009 of the Civil Code of the People's Republic of China represents where genome editing research involving human subjects is explicitly addressed within China's civil legal framework. It stipulates that "medical and scientific research activities related to human genes, human embryos, etc., must abide by laws, administrative regulations and relevant national regulations, and must not endanger human health, violate ethics and morals, or harm public interests"[32].

Book 7 "Tort Liability" of the Civil Code of the People's Republic of China aims to regulate civil relations arising from the violation of civil rights and interests and provides a way to compensate for "the damage of human gene editing", which is mainly reflected in the general fault liability provision of Article 1165 and the relevant provisions of Chapter 6 "Liability for Medical Damage"[33].

Discussion

Some scholars point out that "the significance of this rule is to legalize the above-mentioned research activities, establish new rules for them, and further strengthen the protection of personal dignity and dignity of life" (Wu, Kong, 2023). Regarding the relevant medical and research activities, the Civil Code of the People's Republic of China establishes the criterion of legality

[32] *Criminal Law of the People's Republic of China.* (2020). Available at: http://en.npc.gov.cn.cdurl.cn/2020-12/26/c_921604.htm
[33] *National Health Commission (NHC) of the People's Republic of China.* Available at: https://en.nhc.gov.cn/

as follows: "medical and research activities involving human genes, human embryos, etc., must comply with laws, administrative rules, and relevant national regulations" (Jiayou, Zhongxuan, 2022). The legal wording of this article and the word "shall" indicate that this norm is mandatory and imperative, which means that the subjects of civil turnover carrying out gene editing activities can neither attempt nor agree to exclude the application of this norm (Jiayou, Zhongxuan, 2022). Based on the content, the criterion of legality here is an incomplete rule of law due to the lack of clear constituent elements and legal consequences. It is also an inductive clause, which indicates that the Civil Code of the People's Republic of China is aimed at harmonizing medical and research activities related to human genes and human embryos (Song, Joly, 2021).

The criminal law framework reflects China's absolute prohibition on reproductive genome editing, establishing clear criminal liability for violations. The amendment addresses previous gaps in the legal framework that allowed cases such as the He Jiankui incident to occur without clear criminal consequences. In December 2020, the Amendment XI of the Criminal Law of the People's Republic of China introduced a new type of crime. Article 336a of the Section 5 "Crimes of Impairing Public Health" states that "whoever implants a gene-edited or cloned human embryo into a human or an animal body, or implants a gene-edited or cloned animal embryo into a human body, provided that the circumstances are serious, shall be sentenced to fixed-term imprisonment of not more than three years or short-term custody, and concurrently, a fine. In cases where the circumstances are particularly serious, the offender shall be sentenced to fixed-term imprisonment of not less than three years but not more than seven years, and concurrently, a fine"[34].

Although the Criminal Law of the People's Republic of China has established offences such as illegal implantation of genetic engineering, embryo cloning, illegal harvesting of human genetic resources, and smuggling of human genetic resources, some scholars consider these measures insufficient to meet the needs for regulating the use of new genetic technologies that may arise in the future (Yuan, 2024). Since the use of gene technology includes a high degree of uncertainty and ethical considerations, the regulation of such behavior should be based on the principle of risk prevention (Yuan, 2024). In accordance with the Chinese criminal law system, the relevant behavior can be regulated by interpretation and the use of such crimes, which is dangerous to public safety with the help of hazardous means and crimes intentionally causing health damage. However, this can only play the role of an ex post facto punishment and does not ensure risk prevention in advance (Cao, 2021). Therefore, the most effective way is to identify the source of risks and prevent their occurrence through legislation, i.e., by adopting stricter regulatory measures at the stage of research, development, and use of genes, and by establishing new offenses when necessary. Thus, while the Civil Code and amendments to the Criminal Code (XI) partially address legislative gaps in the field of gene editing technology, related risk management issues remain unresolved. The state regu-

[34] *Ministry of Science and Technology (MoST) of the People's Republic of China*. Available at: https://en.most.gov.cn/

lation faces challenges such as functional uncertainty and vagueness of legislative provisions. The fourth technological revolution, driven by advances in artificial intelligence, microchips, gene editing technology, networked systems and blockchain, poses a range of new legal and ethical risks.

Conclusion

China's regulatory approach has global implications for governance in the sphere of human genome editing. As one of the world's largest funders of genome editing research, China's regulatory decisions influence global research priorities and standards. China's constitutional and regulatory framework for human genome editing research represents one of the world's most comprehensive and rapidly evolving regulatory systems in this field. Built upon constitutional foundations emphasizing public health protection and national security, the framework integrates civil, criminal, and administrative law mechanisms to create a multi-layered system of oversight and control.

The framework emphasizes the precautionary principle, comprehensive risk assessment, and ethical oversight, reflecting the lessons learned from past incidents and demonstrating China's commitment to responsible development of human genome editing technologies. Thus, the relationship between scientific knowledge and innovation in human genome editing depend on the capacity of the regulatory framework to evolve along with technological advances while maintaining public trust. The emphasis on "precautionary" ethical governance may provide a foundation for a new responsible innovation.

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