



**Data Transmission Security and Legal Regulation in Clinical
Application of Human Gene Editing from Perspective of Big Data**

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<i>Article History</i>	<i>Abstract</i>
<p>Received: 1 November 2023 Revised: 15 November 2023 Accepted: 26 December 2023</p>	<p>Gene editing, as an emerging biotechnology, has enormous potential for application but also brings various risks. Considering the current development status of gene editing technology, the criminal regulation of gene editing is based on the theory of risk criminal law. Ethical safety should be protected as a legal interest, and specific criminalization standards should be used to distinguish gene editing for therapeutic purposes, human embryo gene editing, and other types of gene editing behavior. In view of the many problems currently existing in gene editing legislation, at the legislative level, it is necessary to balance the expansion of legal provisions brought about by risk criminal law theory and the exoneration brought about by allowed risk theory, with administrative legal norms in place, and the criminal law should exercise restraint on emerging technologies; At the judicial level, by referring to the understanding of judicial interpretations of similar crimes, corrections can be made to the elements of criminal composition, serious circumstances, and deficiencies in unit crimes.</p>
<p>CC License CC-BY-NC-SA 4.0</p>	<p>Keywords: Human Gene Editing, Data Transmission Security, Big Data, Legal Regulation</p>

1. Introduction

In the late 1990s, a new generation of gene editing technology, starting with Zinc Finger Nuclease (ZFN), has become the most promising gene engineering technology, which can make targeted modifications (knockout, insertion and replacement, etc.) of the target gene, so that the target gene can obtain new characteristics or functions [1], [2], [3]. After nearly 20 years of development and upgrading, gene editing technology includes many types, among which CRISPR-Cas9, CRISPR-Cpf1, BE and PE established based on CRISPR-Cas system are the third generation gene editing technology [4]. CRISPR-Cas system is mainly used in basic theoretical research and partial application research in medicine, biology, physiology and other aspects.

As the core representative of the third generation of gene editing technology, CRISPR-Cas9 technology has developed rapidly, and it has become one of the necessary technologies in the laboratory for its simple operation, fast and efficient. CRISPR-Cas9 gene editing technology uses Cas9 protein to target specific genes in DNA sequence, so as to achieve efficient gene editing

function. In 2013, CRISPR-Cas9 was listed as one of the top ten scientific and technological research advances by Science magazine. At the same time, the Journal of Methodology, a subsidiary of Nature magazine, included it in the 2013 annual research Methods. Nowadays, CRISPR-Cas9 technology has been widely used in various fields such as medicine and biology [5].

At present, CRISPR/Cas9 gene editing technology is mainly used in two aspects in China. On the one hand, it is widely used in animal and plant research for improved breeding, insect resistance of crops, and yield improvement. On the other hand, it is applied to medical research and scientific attempts to treat stubborn diseases, such as gene knockout in fertilized eggs or embryos of zebrafish, mice, rhesus monkeys, fruit flies and other animals, constructing gene knockout models, and conducting research and analysis on growth mechanism regulation, tumor immunotherapy, drug targets, and drug resistance mechanisms.

The clinical applications of gene editing in humans mainly include gene editing techniques. The clinical application of human gene editing can be divided into two ways: in vitro and in vivo, according to the object and method of gene editing. The in vitro approach is a gene editing method outside the body, which requires separating cells or tissues from the body. Then, in the laboratory, specific nucleases are used to increase, delete, or replace the target genes, thus changing the gene composition and function of cells or tissues, and finally, the edited cells or tissues are re-transplanted back into the human body. The advantage of the in vitro approach is the more precise control of the extent and effects of gene editing [6]. Avoid causing unnecessary effects on other cells or tissues, with the disadvantage of requiring complex operation and equipment, and there may be a risk of damage or rejection of cells or tissues. In the body refers to the way gene editing occurs in the human body. Collection, analysis, and transmission of genetic data [7]. It is the basis and premise of the clinical application of human gene editing. It is also the key to realizing personalized, precision, and preventive medicine. Gene data samples can be collected through methods such as blood, saliva, or hair [8], [9], [10].

This article establishes a system that can promote the sharing, utilization, and innovation of genetic data, discusses the data transmission security and legal regulations in clinical applications of human gene editing, discusses threats and legal gaps, and proposes improvement suggestions, aiming to contribute to the healthy development and social supervision of human gene editing.

2. Related Works

2.1 Data Transmission in Medical Care

Data transfer in the clinical applications of human gene editing. It is a complex and critical process involving collaboration and cooperation between multiple links and subjects, as shown in Figure 1. Genetic data needs to be collected from data sources, such as a gene sequencer [16], Gene-editing instrument, or gene database.

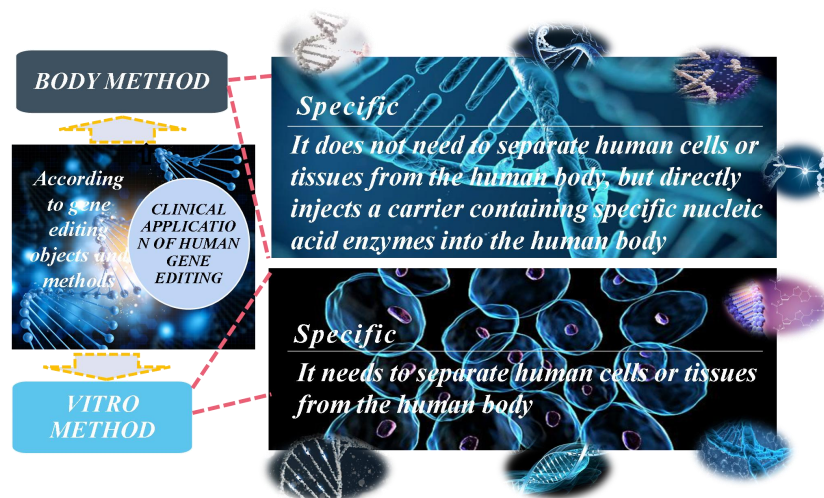


Figure 1. In Vivo and in Vitro Modes of Gene Editing

Figure 2 shows a basic overview of various CRISPR-CAS technologies. The collected data can be transmitted through wired or wireless means to ensure data integrity and improve security. Data

transmission requires the collaborative efforts of various links and entities to improve the security, accuracy, and controllability of data.

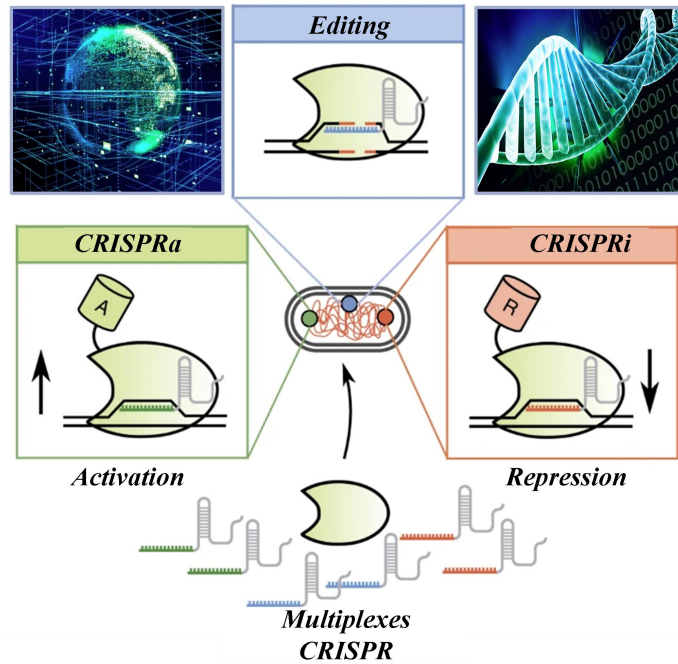


Figure 2. Basic Overview of Multiplex CRISPR-CAS Technology

2.2 Mode of Data Transfer

Data compression technology, a vital component of network data transmission, enhances the efficiency of data transmission by minimizing the volume of data required. The storage, processing, and analysis of genetic data are integral to institutions ranging from hospitals and laboratories to research institutions, government departments, and commercial enterprises.

Table 1. Current Status of Human Gene Editing

Domain	State-of-the-art	Clinical Application
Fundamental Research [17]	Human gene-editing techniques are widely used in basic research, accelerating the understanding of gene function and disease mechanisms	Preclinical study phase, used to validate the treatment strategy and to assess safety and efficacy
Genetic Disease Treatment [18]	Repair the pathogenic genes and treat genetic diseases	Clinical trials are ongoing, such as the use of CRISPR-Cas 9 for β -thalassemia
Cancer Treatment [19]	Improve the recognition and attack ability of immune cells to cancer cells, and improve the effect of cancer treatment	It is still in its early stages, and clinical trials are ongoing and with some initial successes
HIV Treatment [20]	Altering cell surface receptors in HIV-infected individuals and improve the resistance of immune cells to HIV	It is still in its early stage, clinical trials are ongoing, and preliminary results show some efficacy
Tumor Immunotherapy [21]	Improved immune cells to enhance their ability to recognize and kill tumor cells	Clinical trials are ongoing, and CAR-T cell therapy is one of the most successful applications
Organ Transplant [22]	Generate organs of specific genotypes, reduce the risk of rejection from organ transplantation	Still in the laboratory research stage, clinical applications are relatively limited

As shown in Table 1, data storage is the first step in protecting the security of genetic data. Research and medical institutions should choose reliable cloud service providers to ensure that they have professional data protection measures and security certification. And encrypt genetic data, including encryption during data transmission and storage. Adopting a multi-level access control mechanism, setting different levels of permissions and identity authentication to restrict

unauthorized personnel from accessing data. Regularly backup genetic data to prevent data loss and catastrophic events.

2.3 Significance of Data Security Transmission

Data transmission involves multiple links and subjects, including data source, transmission channel, and destination. Each link and the main body may have security risks and risks, such as the reliability of the data source can ensure the accuracy and integrity of the data, the legitimacy of the data destination meets relevant regulations and ethical requirements, the transparency of data transmission can ensure the monitoring and traceability of data transmission process, and the purpose of data use in line with personal authorization and informed consent, etc. The complexity of data transmission increases the difficulty and challenge of data security and the responsibility and obligation of data security.

Data transfer in clinical applications of human gene editing involves genetic data from individuals or populations that are highly sensitive. A genetic gene library is a set or multiple sets of genetic data (genes, gene products, variants, trait expression) stored together with software, so that users can retrieve genetic data from the data, add genetic data, and extract information. A genetic database is a repository of organic data and a resource for understanding how organisms operate. The Human Genome Project largely relies on the internet to obtain new information and share existing data with the world. In addition, there are many online databases that provide various nucleotide sequence and protein information for the public and researchers. All the data on these websites is stored in databases, and the search, access, update, and ongoing annotation of genetic information are all done through databases. Therefore, these websites are often directly referred to as databases.

3. Methodology

3.1 Data Types for Human Gene-editing Techniques

As shown in Table 2, gene editing is a precise scientific technique that can modify gene sequences containing genetic information by inserting, deleting, replacing, etc. [23]. Changes in gene sequence may have an impact on protein expression, and an important function of proteins is to regulate life activities. Therefore, changes in gene sequence can even affect the physiological and biochemical activities of the entire living organism.

Table 2. Data Types and Data Transfer Modes of Gene-editing Technology

Data Type	Data Content	Data Sources	Data Use	Data Transmission Mode
Gene Data	Data containing genetic information for individuals or populations	Gene samples were obtained by blood collection, saliva, hair, skin	Target selection, effect assessment, risk monitoring	Through the network, optical fiber, radio and other communication methods
Clinical Data	Data containing clinical information on an individual or group	Clinical data were obtained through medical institutions, medical equipment, medical records	Indications, safety, efficacy, and persistence of gene editing	Through the network, optical fiber, radio and other communication methods

The main gene editing techniques are shown in Table 3. The clinical translation of gene editing technology is rapidly advancing globally, covering multiple directions such as ZFN technology, TALEN technology, CRISPR/Cas technology, and RNA editing technology. The advantages of ZFN technology lie in diverse gene repair methods, precise gene replacement, and minimal impact on gene expression intensity. However, its disadvantages are also obvious, such as complex design and screening processes, low editability, off target risks, high cytotoxicity, and high treatment costs. In addition, ZFNs face patent blockade issues, which limit their large-scale application and breakthrough progress. As the second-generation gene editing technology, the TALEN technology

that emerged in 2010 has a structure similar to ZFNs, but has low toxicity and is easy to construct. The advantage of TALENs lies in the same cutting efficiency as ZFNs, but their toxicity is usually lower and their construction is easier. Compared with ZFNs and TALENs technologies, CRISPR/Cas9 has a simpler design, lower cost, and better targeting efficiency. RNA editing technology provides a new method for repairing mutations and is gradually becoming an important component of gene editing technology. Unlike permanent changes in DNA editing, RNA base editing is reversible and the editing effect is dose-dependent [24]. The development of gene editing technology has gone through the evolution process from ZFNs to TALENs, and then to CRISPR/Cas9. Each generation of technology has made progress in accuracy, operability, and cost-effectiveness.

Table 3. Clinical Application of Human Gene-editing Technology

Technological means	Principle	Merit	Shortcoming
ZFN [25]	Using the properties of zinc finger protein binding to DNA to design artificial nucleases capable of recognizing specific DNA sequences	High recognition accuracy	Difficult in design, high in cost, and low in efficiency
TALEN [26]	Using the properties of transcription activators binding to DNA to design artificial nucleases capable of recognizing specific DNA sequences	A wide range of identification	Complex structure, large size, difficult to transfer
CRISPR [27]	Using the bacterial immune system, a complex composed of Cas protein and crRNA, recognizes and cleaves natural nucleases of specific DNA sequences	Simple operation, high efficiency, and low cost	Recognition accuracy is low and may produce nonspecific cleavage

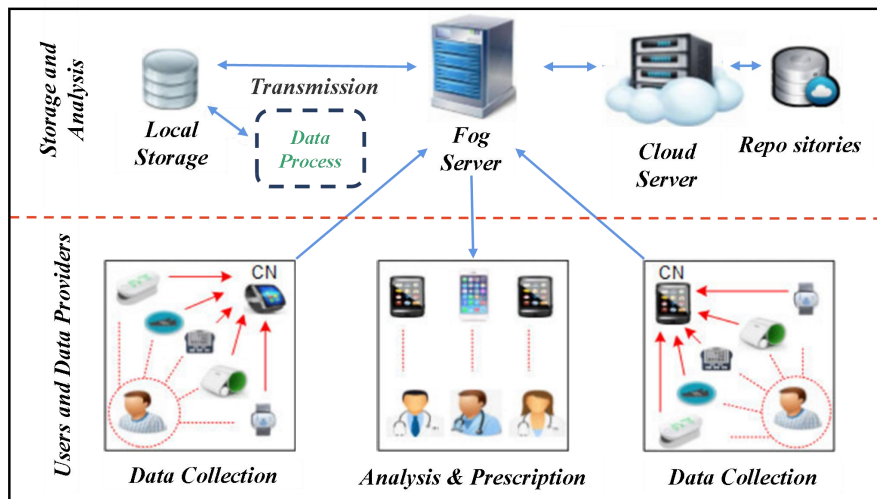


Figure 3. Medical Data Transmission Process

The data transmission mode is a crucial link in human gene editing technology. Current standard data transmission methods include network transmission, Bluetooth transmission, and USB transmission [28], as shown in Figure 3. Mutation detection data refers to the data obtained from testing patients for a mutation in a specific gene. With these data, it is possible to determine whether patients carry specific pathogenic genetic mutations, allowing for genetic counseling and disease risk assessment. In addition, mutation detection data are also crucial for screening and diagnosing inherited diseases in families.

In addition, the cell sample data refers to the data obtained from the cell samples taken from the patient. These data are usually used in the experimental process of gene editing, including detecting editing efficiency, verifying gene expression after editing, etc. Through cell sample data, researchers can evaluate the efficacy and safety of gene editing technology, providing an essential reference for subsequent clinical applications.

3.2 Mode of Data Transmission

Network transmission is data transfer from one computer to another over the Internet. This transmission mode has the advantages of high efficiency and convenience, but it also has security risks. Therefore, some measures need to be taken to protect data security during data transmission, such as encrypted transmission, access rights management, etc., as shown in Table 4.

Table 4. Specific Modes and Characteristics of Data Transmission

Data Transmission Mode	Specific Way	Characteristic
Network Data Transmission	Circuit exchange, packet exchange, packet exchange	Long-distance, high-speed, multi-target data communication, but there may also be network delay
Bluetooth Data Transmission	Bluetooth technology, Bluetooth Mesh technology	Short distance, low power consumption, low cost of data communication, but there may also be slow transmission speed
USB Data Transmission	Parallel transmission, serial transmission, synchronous transmission	High speed, high reliability, high compatibility of data communication, but there may also be a short transmission distance

Another common form of data transmission is Bluetooth transmission, which transfers data from one device to another. The advantage of Bluetooth transmission is its high security, which can prevent data from being illegally obtained during transmission. However, it is limited by the slow transmission speed and limited transmission distance.

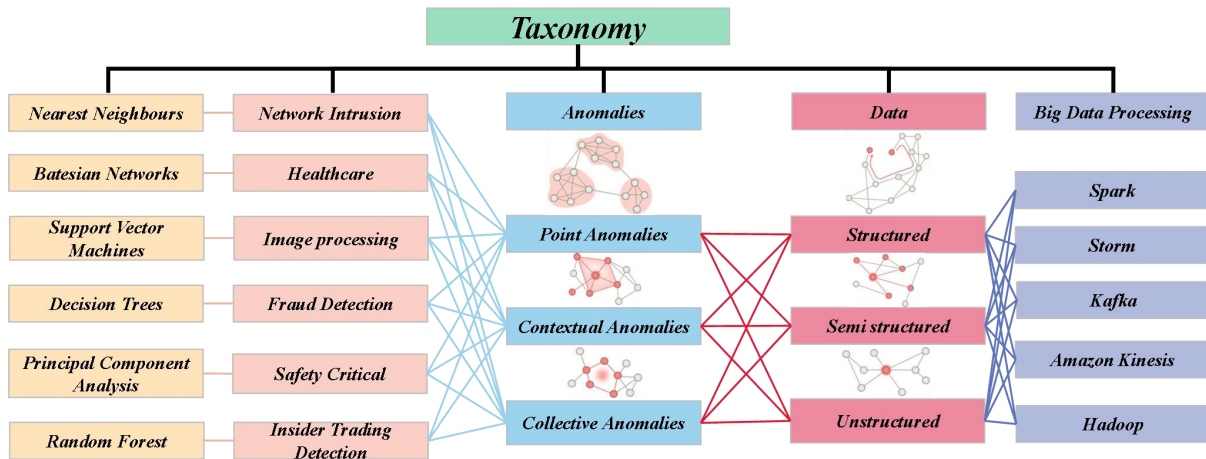


Figure 4. Introduction of Transmission Details

The data acquisition and transmission methods involved in human gene editing technology must attach great importance to data security and privacy protection. The appropriate transmission mode should be selected according to the specific situation, as shown in Figure 4. Take corresponding security measures to ensure the integrity and confidentiality of the data to promote the safe and sustainable development of human gene editing technology in clinical applications.

4. Results and Discussion

4.1 Threats to Data Transmission Security and Common Security Measures

During data transmission, intermediary attacks and data tampering may occur, so corresponding measures must be taken to prevent them. Figure 5 shows the corresponding

preventive measures. In the process of data interaction, the logical flow of data plays an important role in determining the processing and flow path of data during transmission and exchange. To ensure that information is not tampered with during transmission, it can be sent together by forming an information summary. After receiving the information, the receiver can reorganize the information summary and compare it to determine whether the information has been modified. For the first and third items, asymmetric encryption can be used.

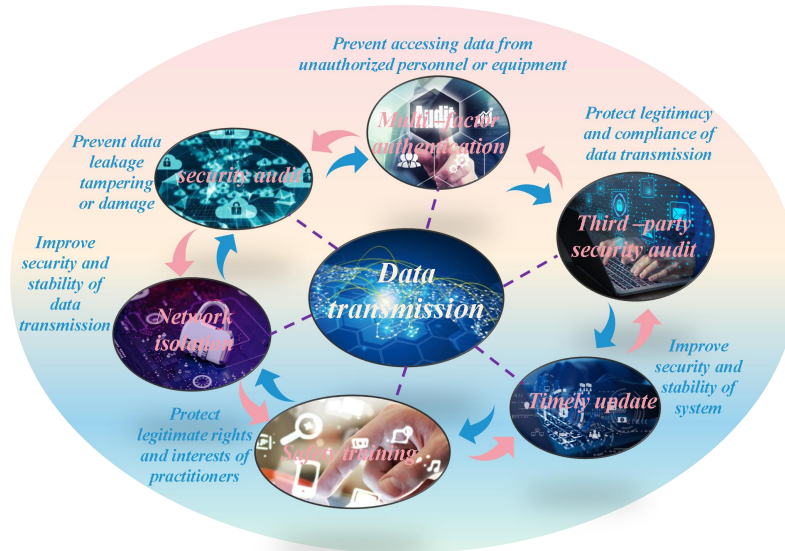


Figure 5. Specific Description of the Data Transmission

To address these threats, consider the following extended data transmission security measures:

- **Network isolation:** Network isolation refers to separating the data transmission networks used for clinical gene editing applications from other networks, which limits physical access to the system and helps reduce the risk of hacking, as shown in Table 5. This standard data transmission security measure can effectively prevent data from being illegally stolen, tampered with, or destroyed. There are many ways of network isolation. For example, firewalls, routers, and switches can be used to divide different network areas and access rights; dedicated network lines, optical fiber, radio, and other communication modes can be used to establish an independent data transmission network; encrypted virtual private network (VPN) can be used to create a secure data transmission tunnel.

Table 5. Detailed Introduction of Network Isolation Measures in Data Transmission

Network Isolation and Security Measures	Merit	Shortcoming
Physical Isolation	Effectively prevent external direct attacks and interference, improve network security	It cannot meet the service requirements of real-time data synchronization between networks, which is inconvenient for users to use and has low resource utilization rate
GAP	Realize the orderly, controllable and auditable transmission of the data between the networks	Malicious data-driven attacks that hide malicious code in an electronic document and send it to the target network, which pose a security threat to the internal network through electronic documents with malicious code function
Agreement Isolation	Realize the orderly, controllable and auditable transmission of data between networks	There are still security risks, for example, errors or vulnerabilities that may occur in the process of protocol conversion
One-way Transmission	Realize the one-way	Unable to realize the bidirectional

	transmission of data between networks	transmission of data between networks, and cannot meet the business requirements of two-way data exchange
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- **Security audit:** To guarantee the secure and dependable transmission of data in the clinical application of human gene editing, it is imperative to establish a comprehensive logging and monitoring system that provides real-time surveillance and examination of the data transmission process, as illustrated in Figure 6. This approach aids in promptly identifying irregularities and implementing appropriate measures, thereby mitigating the risks of data leakage, alteration, or corruption. It further safeguards patient privacy and rights while enhancing the efficiency and integrity of data transmission.

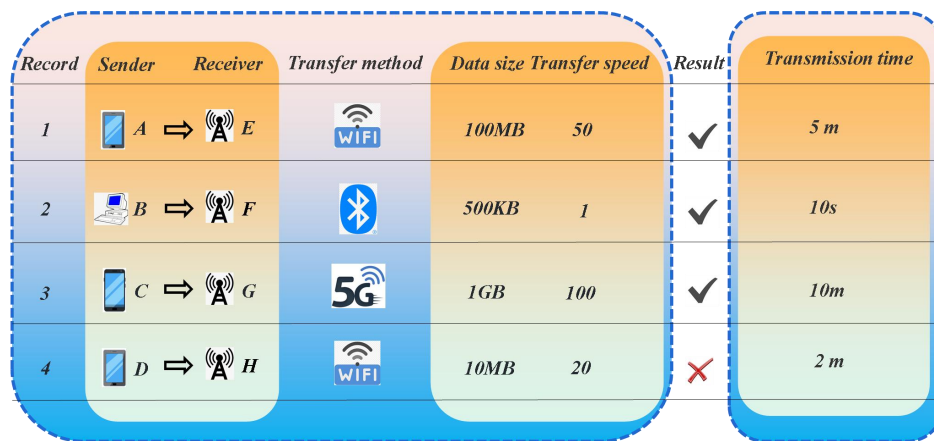


Figure 6. Data Transmission Information Diagram

Multifactor authentication: Data access in the clinical applications of human gene editing is an empathetic and essential link that requires strict security control and management, as shown in Table 6. To increase data access security, multiple authentication mechanisms can be introduced, such as fingerprint recognition, iris scanning, voice print recognition, etc., which can effectively identify and verify the identity of data visitors and prevent unauthorized personnel or devices from accessing the data.

Table 6. Multi-factor Authentication Measures Based on Data Transfer

Multi-Factor Authentication Security Measures	Merit	Shortcoming	Common Methods
Multifactor Authentication (MFA)	Can effectively protect the organization from unauthorized access and improve data security and compliance	May increase the authentication burden of users and reduce the user experience	SMS, email, phone calls, authentication applications, physical tokens, biometrics
No Password free Authentication	It can reduce the risk of phishing attacks and voucher filling attacks	There are still weaknesses of ownership, inherent, and behavioral factors	Fingerprints, facial recognition, physical token, behavior analysis
Adaptive Authentication	Can achieve the balance between data security and user experience, improve data security and efficiency	Extensive resources and expertise need to be deployed and user behavioral data need to be collected and analyzed	Artificial intelligence, machine learning, behavior analysis, risk assessment

Based on the existing requirements for cross-border transmission of human genetic resources, such as cross-border cooperation projects between gene therapy and gene editing technology

enterprises and institutions involving the utilization of human genetic resources in China, corresponding regulatory requirements need to be followed according to different utilization situations, and administrative permits, filing, prior reporting, and information backup procedures need to be processed. The research and application of gene editing technology should have transparency and information disclosure. Relevant research institutions, government regulatory agencies, and scientists must share technical details and research results, and engage in open and sincere discussions.

In order to provide clear guidelines for scientific research on gene editing technology, legislation and regulatory documents in the administrative field should at least make it clear to researchers engaged in related work what acts may constitute crimes. However, according to the current regulations, no effective guidance can be provided, which also makes the criminal legislation and administrative legislation of gene editing deviate from each other and run independently on their own tracks. For example, for the word "illegal" in "illegal implantation of gene editing and embryo cloning crime", it is difficult to determine which law has been violated, and it is difficult to find legal provisions that can be used as a basis in administrative legislation.

In view of this problem, administrative legislation can be properly fine-tuned to meet the formal requirements. For example, add a simple footnote to the law that can be invoked, such as "the conduct constituting a crime shall be convicted and punished in accordance with the criminal law." Such a provision could establish a clearer link between administrative and criminal legislation. Through such fine-tuning, administrative legislation can provide clear legal guidance, so that scientific researchers engaged in gene editing technology can clarify which behaviors may constitute crimes, and provide legal basis for the investigation of related crimes.

4.2 Legal Regulation of Data in Clinical Application of Human Gene editing

With the acceleration of scientific and technological progress and industrialization, people are more and more worried about the increase of uncertainty. The concept of criminal law in risk society has begun to be paid attention to, and legislators tend to adopt more criminal legal norms to prevent the occurrence of dangerous events. At the same time, however, the theory of "permissible risk" has emerged in the same social context. Risk criminal law theory and permissible risk theory can be said to be two complementary aspects of criminal law. The allowed risk theory means that with the development of science and technology, there are some unavoidable dangerous behaviors in social life. Modern life would become untenable if excessive precautions were taken to prevent harmful outcomes. At present, the response of criminal law to risk mainly takes "social equivalence" as the standard. Human gene editing is clearly the result of technological progress. On this issue, criminal law should be cautious about the expansion of the penalty scope brought by the risk criminal law theory and the exonerating of the perpetrator brought by the permissible risk theory.

Gene editing behaviors should be treated categorically, including somatic gene editing for therapeutic purposes, human embryo gene editing, and gene editing for other purposes. The risks faced by different types of behaviors are also different, and gene editing therapy and germline editing are the most controversial risk concentration points. This must be done when gene editing therapies are needed to treat cancer and keep patients alive, even when there is a high risk of death due to treatment failure. As a result, gene-editing therapy is more likely to be considered a permissible risk and justified than other treatments. For any treatment behavior, it should be safe, necessary and effective. The treatment behavior that has to be adopted in order to save the life of the patient meets the conditions for the establishment of emergency risk avoidance. If the treatment is successful, it does not need to consider whether it is a permissible risk behavior. It is necessary to determine whether the doctor constitutes a condition of negligence. If the doctor performs the objective duty of care, it does not conform to the objective constitution of negligence. Otherwise, it is necessary to further determine whether the doctor was negligent. In general, negligence should be denied if the risk was recognized prior to treatment or if a more dangerous event than expected occurred during treatment.

5. Conclusion and Future Work

Gene therapy and gene editing technology have demonstrated their unique clinical value, attracting a portion of high-quality domestic and foreign biotechnology companies to engage in related research. The industry is developing rapidly and the market size is constantly growing. Establish a gene editing technology system with independent intellectual property rights, and

develop new gene therapy technologies for major genetic diseases, infectious diseases, malignant tumors, etc. While having broad market development prospects, the industry regulation of gene therapy and gene editing technology will gradually move towards systematization, standardization, and strictness. Relevant entities should strictly abide by relevant laws and regulations, constantly pay attention to the latest regulatory trends, conduct relevant research and cooperation in compliance, optimize product pipelines and actively promote product research and development progress, strive for the early registration and marketing of corresponding drugs, and bring benefits to the lives and health of patients at home and abroad.

The remarkable progress of CRISPR technology signals a promising trajectory for its enduring impact on human health and beyond. As technology marches forward, we envisage the ever-broadening applications of gene editing across diverse fields. Yet, the moral and ethical considerations that accompany it compel us to confront and address them collaboratively. The gene editing industry's future promises to be a landscape rich in opportunities and equally charged with challenges, deserving of our closest attention and thorough exploration.

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