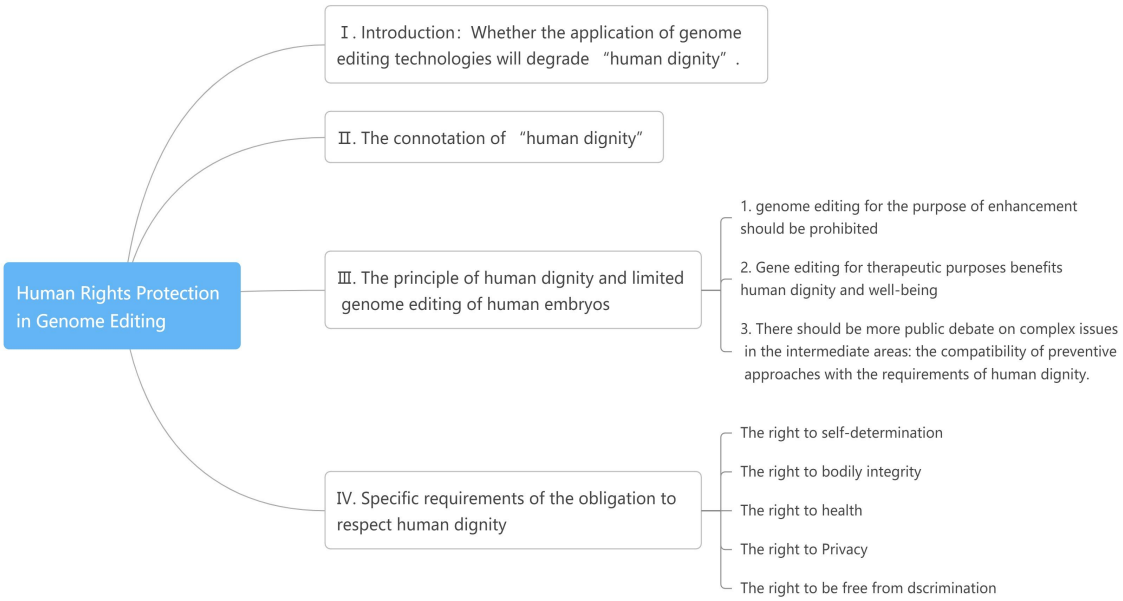
Title: Human Rights Protection in Genome Editing

Author: SHi Jiayou & HU Xinping

I. Structure of the article



II. Research purpose and significance

■ **Purpose:**

This article attempts to introduce the perspective of "human rights" in the framework of multi-dimensional governance of human embryos genome editing activities, build the framework of behavior patterns in line with human rights protection standards, and determine the specific practices of each subjects or entities in line with human rights obligations under this framework.

■ **Significance:**

The discussion on the clinical application and legal regulation of genome editing has gained unprecedented attention worldwide with the emergence of the third-generation technology CRISPR/ Cas-9 and the incident of the genome-edited infants by He Jiankui. At present, not enough attention is being paid to the protection of individual's rights in the application of genome editing technologies.

Introducing the human rights perspective into the multi-dimensional governance of human genome editing activities would help define boundaries for the behaviors of stakeholders such as the state, researchers, ethics committee members, and the public, and clarify specific practices of these subjects or entities to meet the requirements of human rights obligations.

III. Research object and question

■ **Object**

The various human rights involved in the practice of human genome editing.

■ **Question**

Taking into account the specific scenarios of human genome editing technologies to explore how to set corresponding principles and rules for the protection of rights in genome editing practices.

IV. Type of scholarship

■ **Doctrinal:**

Doctrinal: The author provides a descriptive and detailed analysis of domestic and international law relating to human rights, including the PRC Constitution, the Civil Code and several international human rights conventions.

■ **Theoretical:**

A. In exploring the connotation of "dignity", the author reviews the history of human rights theory and explains the word "dignity" in jurisprudence.
B. In exploring the "right to informed consent" for genetically edited embryos, the authors cite and analyse various doctrines to justify the "legitimacy of intergenerational consent" of parents.

V. Information

The primary information sources of this article：

■ Multiple international human rights conventions or declarations:

- the *Universal Declaration of Human Rights* in 1948
- the *Declaration of Helsinki*
- the *International Covenant on Civil and Political Rights*
- the *international Covenant on economic, Social and Cultural Rights*

■ International Medical Research Reports:

- the *Report on Heritable Human Genome editing 2020*（《人类可遗传基因组编辑报告 2020》）
- the *2016 International Ethical Guidelines for Health-related Research Involving Humans*（《涉及人的健康相关研究国际伦理准则: 2016 年版》

■ Domestic laws:

- the *Constitution of the people's Republic of China*
- the *Civil Code of the people's Republic of China*

VI. Main Argument

Whether the application of genome editing technologies will degrade "human dignity"?

VII. Argumentation

■ **Firstly, the author discusses the connotations of human dignity.**

- In the subjective sense: The core value of dignity is autonomy and self-determination, which emphasizes self-determination of one's own affairs and interests.
- In the objective sense: The core value of dignity is humanity, emphasizing the intrinsic and basic respect that human beings deserve because of what they are. In other words, a member of the human family must respect the human values that are common to all.

■ **Secondly, the author discusses the different purposes of gene editing in human embryos.**

1. Genome editing for the purpose of enhancement

The enhancement of specific traits of human being through scientific and technological means, the optimization of an individual's physical or psychological conditions, and the enhancement of an individual's intellectual and physical abilities, is completely against human dignity and well-being.

2. Genome editing for the purpose of treatment

A. In the context of the inadequate development of existing technologies, it is suspected that germline genome editing will be carried out hastily, and the edited infants will be used as a tool to promote the development of the technologies. The edited infants may be a lifelong experimental subject. So the use of germline genome editing technologies（生殖系基因编辑技术） to carry out gene therapy for pregnancy at the current stage violates human dignity.

B. However, with the development of technology, genome editing for therapeutic purposes is actually in line with the dignity of genome-edited infants, provided that the technology is ensured to be safe and meets all the legal requirements.

3. The intermediate area：

Actually, there is no clear distinction between treatment and enhancement. The typical situation is: enhancing the body's resistance to avoid any future disease, is the prevention of a possible disease a treatment or an enhancement?

In view of this situation, the author believes that the principle of proportionality should be applied to judge the legitimacy of the purpose of genome editing and the necessity of embryo genome editing methods, such as treatment limited to severe conditions for which no alternative treatment is available.

VIII. Conclusion

The principle of human dignity implies that limited genome editing of human embryos. Genome editing for enhancement purposes should be prohibited as it degrades "human dignity", while those for therapeutic purposes, which is a legitimate extension of an individual's right to reproduction, health and free development, cannot be completely prohibited on the grounds of general public interest. As for the intermediate areas between enhancement and treatment, the author believes that there should be more ethical studies and interdisciplinary discussion on complex issues.

IX. Implications

1. The author breaks down the human rights in gene editing into various specific rights, including the right to informed consent, the right to bodily integrity, the right to health, the right to privacy and the right to be free from discrimination. Meanwhile, the author argues how each of these rights can be safeguarded, thus setting boundaries for the behaviour of all stakeholders, including the State, researchers, members of ethics committees and the public.

2. As the most important aspect of human rights protection, the State has the obligation to fully guarantee the fundamental human rights of gene editors. This article provides suggestions for legislative activities in this field by discussing human rights protection and the limits of gene editing technology.

THE JOURNAL OF HUMAN RIGHTS
VOL. 21 NO. 5 OCTOBER 2022

Human Rights Protection in Genome Editing

SHI Jiayou[*] & *HU Xinping*[**]

Abstract: *Introducing the human rights perspective into the multi-dimensional governance of human genome editing activities would help define boundaries for the behaviors of stakeholders such as the state, researchers, ethics committee members, and the public, and clarify specific practices of these subjects or entities to meet the requirements of human rights obligations. Based on the human dignity principle, humans must never be used as a means to an end in scientific research. The right to physical and mental health requires the implementation of the principles of informed consent, the primacy of life, and risk control in genome editing, as well as the proper treatment of embryos. The right to privacy corresponds to the confidentiality obligations and non-intervention obligations of relevant parties, and the protection of sensitive personal information points to the special compliance requirements regarding information processing. Differential treatment of genome-edited humans requires objective and reasonable justification, and should also meet the requirements of the proportionality principle.*

Keywords: genome editing ◆ human dignity ◆ right to physical and mental health ◆ right to privacy ◆ personal information protection

I. Introduction

Genome editing has developed rapidly in the past few decades. This technology is undoubtedly the most influential in contemporary biology because of its advantages in modifying genetic mutations, treating inherited rare diseases, and understanding early human development. At the same time, its safety and effectiveness are still controversial. Any reckless use of this technology may pose a threat to human dignity and biological security, and it is therefore highly controversial as well. The discussion on the clinical application and legal regulation of genome editing has gained unprecedented attention worldwide with the emergence of the third-generation technology CRISPR/ Cas-9 and the incident of the genome-edited infants by He Jiankui. At present, most Chinese scholars take the overall regulatory framework for genome editing

* SHI Jiayou (石佳友), Doctor of law and Researcher at the Research Center of Civil and Commercial Jurisprudence of Renmin University of China.

** HU Xinping (胡新平), Master of law and Researcher at the Research Center of Civil and Commercial Jurisprudence of Renmin University of China. This paper is a phased result of the project "study on the legislation of genome editing in human embryos" (Project No. 19SFB2035), a National Rule of Law and Legal Theory Research Program by the Ministry of Justice in 2019.

as the research object. From top-level design, they have studied the governance model and consensus formation mechanism, and put forward constructive suggestions such as improving the construction of the national legal system and regulatory system for biotechnology, improving the professional capacity of the Ethics Review Committee, promoting the self-discipline construction of the science and technology community, strengthening public participation, and actively participating in the shaping of international standards.[1] However, not enough attention is being paid to the protection of individual's rights in the application of genome editing technologies. Therefore, this paper attempts to introduce the perspective of "human rights" in the framework of multi-dimensional governance of human embryos genome editing activities, build the framework of behavior patterns in line with human rights protection standards, and determine the specific practices of each subjects or entities in line with human rights obligations under this framework.

In the development of human rights theory, the modern Anglo-Saxon view of human rights relates the protection of human rights in the constitution to the opposition to state interference, and limits the subject of human rights obligations to the state. Later, the human rights concept of the French transcendental *de lege lata* constructed a layered protection of human rights — human rights are regarded as a value beyond *de lege lata*. After a constitution establishes the positive rights of individuals in relation to the state, the state formulates ordinary laws to make other human rights positive, such as adjusting the human rights conflicts among citizens through civil law. Constitutional norms can offer the whole legal order the reference and inspiration in terms of concept, classification and reasoning, while the contents of a civil law and other general laws provide paradigms for the enforcement and application of constitutional norms.[2] The human rights enshrined in a constitution interact dialectically with the human rights in the civil law and other general laws, which jointly protect the free living and development of people, and unify with the concept of human rights in the transcendental *de lege lata*.[3] With the recent development of international human rights law, the "full effectiveness" of human rights is flourishing. Human rights cover not only violations by the state against individuals, but also those among individuals.[4] For example, in a civil contractual relationship, if an individual's fundamental rights are violated, he/she can directly stand against the other party and claim that the contract is invalid.[5] Thus, the subjects or entities of human rights obligations are not merely limited to states, but can include individuals and social groups. In the case of

1. Zheng Ge, "Towards a Constitutional Life: How the Law Responds to the Risks in the Application of Genome Editing Technologies", *Studies in Law and Business* 2 (2019): 3-15. Peng Yaojin and Zhou Qi, "China's Approach to Biotechnology Reform and Ethical Challenges," *Bulletin of Chinese Academy of Science*s 11 (2021): 1288-1297.
2. Shi Jiayou, "The Relationship between Human Rights and Right of Personality: From the Perspective of Independent Book of Personality Rights in the Civil Code," *Law Review* 6 (2017): 102.
3. Huang Yuxiao, "On the Invalidity of Constitutional Fundamental Rights to the Third Party," *Tsinghua University Law Journal* 3 (2018): 186-197.
4. Manfred Nowak, *Introduction to the International Human Rights Regime*, translated by Liu Huawen, edited by Sun Shiyan (Beijing: Peking University Press, 2010), 46-51.
5. Shi Jiayou, "The Relationship between Human Rights and Right of Personality", 98.

genome editing, they can include researchers, clinical study sponsors, ethics committees, the public, etc. Among them, the right to physical and mental health discussed in this paper mainly involves the first three subjects or entities of obligations. And the right to privacy, the right to personal information protection, and right to be free from discrimination all interact with the public, so it is inevitable that there are human rights requirements for the public behavior.

Based on this, this paper will take the human rights obligations of different subjects or entities as the research object to discuss the protection of human rights in genome editing. Considering that human dignity is "the legitimacy source and logical premise of human right" and "provides legitimacy proof for human rights theory"[6], this paper chooses human dignity, the highest value, as the key point, takes into account the specific scenarios of human genome editing technologies, deeply analyzes the right to self-determination, the right to body, the right to health, the right to privacy, the right to protection of personal information and the right to be free from discrimination, which all came into being based on human dignity, so as to set corresponding principles and rules for the protection of rights in genome editing practices.

II. Human Dignity and Protection of Human Dignity

After the genome-edited infant incident in Shenzhen, some scholars believe that the development of human genome editing technologies enable humans to assume the role of "playing God", changing or even creating ourselves through human intervention instead of nature. However, when human beings gain extreme freedom and "try to transcend the concept of human beings and become another higher existence"[7], the first thing that needs to be discussed is whether the application of genome editing technologies will degrade "human dignity".

A. The connotation of "human dignity"

"Dignity" is a key concept often invoked in national constitutions, international treaties, human rights declarations, religious teachings, and various philosophical works. It is important to emphasize that dignity is a fundamental right without any restrictions or derogation and without allowing for any exceptions — a point even higher in value than the right to life. Because in many countries, including China, the death penalty can be applied according to law to deprive an offender of life, but even those condemned to death who are about to be deprived of their lives have a fundamental right to respect for their dignity. In the field of bioethics, the dilemmas are full of moral paradoxes, and conflicts of rights mean the analytical principles used in the academic field are unable to be applied to the evidence of academic opinions. Therefore, "dignity", a more basic concept and value, comes into play and becomes a commonly used concept in the field of bioethics.[8] This is the discussion in the field of

6. Yu Keping, "On Human Dignity: A Political Analysis," in *Peking University Political Science Review*, vol. 3 (Beijing: The Commercial Press, 2013), 12-14.

7. Zhu Zhen, "Is Genome Editing Necessarily against Human Dignity?", *Law and Social Development* 4 (2019): 168.

8. Han Yuehong, "Human Dignity in the Context of Bioethics," *Studies in Ethics* 1 (2015): 108.

genome editing.

Opponents of genome editing argue that the application of these technologies objectively modifies and manipulates human genetic resources, changes the natural mode of human birth, and "reproduction" becomes a stylized "production" of human beings, which constitutes the destruction of the basic attributes of human beings. At the same time, genome editing has the risk of instrumentalizing and objectifying human beings, bringing the human community into multiple crises in fields such as morality, security and social cognition. However, supporters also take human dignity as the basis of debate. Advocates in favor, represented by Dworkin, argue that human dignity depends on human autonomy and self-determination, and that the state should remain neutral before citizens' reproductive freedom. At the same time, the direct goal of genome editing is undoubtedly to pursue a more ideal state of life, which is different from the blind pursuit of blood and race in ancient eugenics. This scientific reproductive choice prevents natural defects, which not only benefits individual dignity, but also promotes public interests.[9] As a result, both sides of the debate are based on the same concept, but end up with completely different views.

The important reason for this paradoxical phenomenon is that the basic category of "dignity" has rich meanings, including subjective dimensions and objective dimensions, which is the reason why it has become a widely used debating weapon. The core value of dignity, in the subjective sense, is autonomy and self-determination, which emphasizes self-determination of one's own affairs and interests. On the contrary, the core value of dignity, in the objective sense, is humanity, emphasizing the intrinsic and basic respect that human beings deserve because of what they are. In other words, a member of the human family must respect the human values that are common to all. Therefore, the basic bottom line for a human to be a human is non-negotiable and non-derogable. For example, Article 1 of the *Universal Declaration of Human Rights* in 1948 declares that "All human beings are born free and equal in dignity and rights." It can be seen that the objective sense of dignity constitutes a certain restriction on the subjective sense of dignity. As people have pointed out, "If we believe that respect for human dignity is the fundamental value of our society, then personal preferences or choices that are inconsistent with the respect for human dignity should be off limits."[10]

As far as the legal norms in China are concerned, the *Constitution of the People's Republic of China* (hereinafter referred to as "the *Constitution*") contains two articles concerning the discussion of this issue, which are Articles 33 and 38. In terms of the relationship between human rights and human dignity, human rights protection is the fundamental way to realize human dignity, and human dignity is the value goal of human rights protection.[11] Therefore, some scholars believe that the content of "the state respects and protects human rights" in Article 33 is the normative basis of China's protection of human dignity. It means that the protection of human dignity is part

9. Yu Wei, "Human Genome Editing from the Perspective of Constitutional Law," *Fujian Tribune (Humanities and Social Sciences Edition)* 3 (2021): 189-194.

10. Deiyck Beyleveld and Roger Brownsword, "Human Dignity," *Bioethics and Biolaw* 1 (2001).

11. Han Yuehong, "National Dignity and Human Dignity," *Journal of Kunming University of Science and Technology(Social Sciences)* 1 (2014): 14.

of China's *Constitution*, which makes human rights and human dignity upgrade from value to positive constitutional principles.[12] More scholars claim that the provision of Article 38, which is "inviolability of human dignity," has played a role in protecting human dignity and can serve as the foundation of the whole system of basic rights. Among them, the connection of "personal dignity" and human dignity can be achieved through semantic interpretation, or through the interpretation of the connection between the preceding and following paragraphs of this article.[13] The interpretation of the meaning of the concept "personality" can also be used as a method.[14] In general, whether it is based on Article 33 or Article 38, the value consensus among scholars regards the protection of human dignity as the due meaning of China's *Constitution*.[15] Besides, it is not limited to "freedom from insult, slander and false accusation," but contains more value connotations based on the content of "dignity" itself and the design of the whole rights system of China's *Constitution* — "freedom from domination" "freedom from harm" "equality and freedom from discrimination" and "the possibility of free participation in life."[16] Article 109 and Article 990 of the *Civil Code of the People's Republic of China* (hereinafter referred to as the *Civil Code*) are in line with the expression of the *Constitution* and specifically stipulate human dignity, and the concept of "life dignity" is proposed in Article 1002. It can be argued that "dignity of life" is actually a sub-concept of human dignity, with special emphasis on the respect and protection of human life forms, corresponding to the right to life, the right to the body and the right to health. In a negative sense, it includes freedom from torture and inhumane treatment and from threats to life. And in the positive sense, it means that there is material and medical security to maintain a life of minimum dignity, and there is personal freedom and security.[17]

B. The principle of human dignity and limited genome editing of human embryos

In fact, the treatment of diseases based on human genome editing only involves the edited individual, which is not substantially different from other widely used medical and clinical interventions, and does not cause a big impact on people's ethical cognition.[18] Besides, the treatment, which is based on extensive scientific research, could prevent as many adverse outcomes as possible while offering hope of a cure for patients with rare genetic diseases. Therefore, the application of genome editing technologies in somatic cell gene therapy is generally ethically acceptable. And it can be

12. Wang Hui, "The Concept and Institutionalization of Human Dignity," *China Legal Science* 4 (2014): 117.
13. Lin Laifan, "Human Dignity and Personal Dignity: A Case Study on the Interpretation Scheme of Article 38 of China's Constitution," *Zhejiang Social Sciences* 3 (2008): 51-53.
14. Bai Bin, "The Norms of Human Dignity in the Constitution and Its Status in the System," *Law and Economy* 6 (2019): 51-66.
15. Zhu Hu, "How does the Personality Right Become a Civil Right?" *Law Review* 5 (2021): 66-67.
16. Wang Xu, "The Theory of Dignity in Constitution and Its Systematization," *Chinese Journal of Law* 1 (2016): 53.
17. Han Yuehong, *Human Dignity from the Perspective of Bioethics* (Kunming: Yunnan Education Publishing House, 2017), 69.
18. Sun Haibo, "Legal Philosophy of Genome Editing," *Journal of Comparative Law* 6 (2019): 107.

considered that the development of somatic cell gene therapy meets the requirements of human dignity. However, under germline genome editing, genome editing for therapeutic purposes and that for enhancement purposes have different effects on human dignity. The situations of instrumentalization, manipulation of life, distortion of self-esteem and dignity,[19] which are what scholars think of will happen in genetically edited individuals, will not happen in genome editing for therapeutic purposes. Rather, they will mostly occur in genome editing for enhancement. Because, according to Kant's famous theory, all human beings have the same moral value, and therefore they should be treated only as ends and not as means.

First of all, in the context of the inadequate development of existing technologies, it is suspected that germline genome editing will be carried out hastily, and the edited infants will be used as a tool to promote the development of the technologies. The edited infants may be a lifelong experimental subject. So the use of germline genome editing technologies to carry out gene therapy for pregnancy at the current stage violates human dignity. However, with the development of technology, genome editing for therapeutic purposes is actually in line with the dignity of genome-edited infants, provided that the technology is ensured to be safe and meets all the legal requirements, for the following reasons. First, the argument that "human dignity is embodied in the 'spontaneous' nature[20] of the most fundamental genetic material of the human body" used by scholars is not justified and reasonable here. The spontaneous, orderly control of genes should not be disturbed by external means. But gene therapy deals with the misexpression of genes, often for rare genetic diseases for which there are no alternative treatments, and genome editing is the only hope for patients. In this case, the edited individual is not a tool, but exactly the purpose of treatment. Then, how can it constitute a derogation of human dignity? Second, scholars believe that "in the practice of genome editing, it is inevitable to use biochemical reagents to control the reaction of genome editing, which poses a threat to the life of genome-edited infants."[21] In fact, when genome editing is used as a drug or technology in clinical practice, it will be approved by the state only after its safety and efficacy are proved. And in individual practice, it needs to go through strict ethical and biosafety reviews. Simple artificial selection is crude for delicate life. After all, limited by the current scientific and technological development and cognitive level, human beings are still unable to completely understand the mystery of the evolution of life. But limiting genome editing to fixing specific genetic mutations and treating specific rare genetic diseases merely restores the integrity of an individual's genes, not simple artificial selection. Third, it is also unreasonable for scholars to argue that "the perception of self-evaluation and external evaluation of the genetically edited individuals cannot be predicted, and their personal dignity is degraded."[22] Firstly, because of the lack of possibility of obtaining consent from future edited infants, as discussed later, intergenerational consent will

19. Liu Yafei, Ma Xiaomin, Sun Hongyan and Wang Yunling, "The Challenge of genome-edited infants to Human Dignity," Medicine & Philosophy 11 (2019): 34-35.

20. Ibid., 34.

21. Ibid.

22. Ibid., 35.

be achieved by closely protecting the parents' right to informed consent. Second, in the rational sense of the average person, it is clearly in the individual's best interest to choose between genome-edited recovery and unedited early death or serious disease.[23] Briefly speaking, after strict ethical review, "gene therapy that meets the legal requirements can help potentially vulnerable infants to achieve a health status similar to that of healthy people at birth, on the basis of which they can achieve independent development and personality shaping, and then lead a dignified life."[24] Third, the examples used by the scholars to demonstrate the frustration of the dignity of the edited individuals, such as "those perceived as cheaters who easily gained high intelligence and physical strength without effort,"[25] are clearly within the discussion scope of gene enhancement and therefore are of no relevance to gene therapy. In addition, from the perspective of positive arguments, genome editing for therapeutic purposes is a reasonable extension of the individual's right to reproduction, health, and free development, and cannot be completely prohibited on the grounds of general public interest.[26]

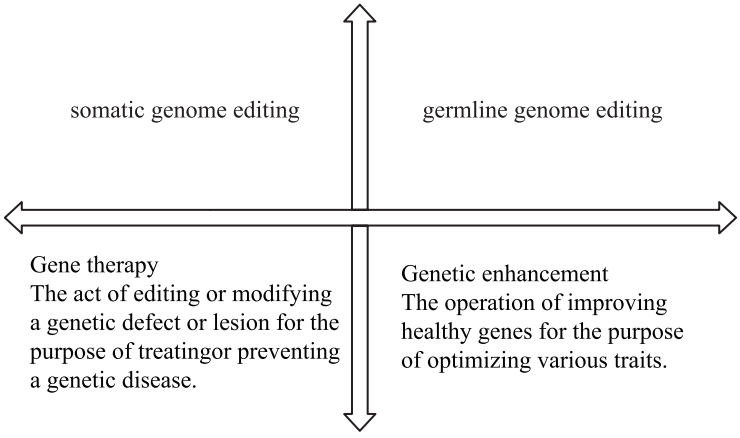


Figure 1 Different scenarios of application of genome editing technologies

However, genome editing for the purpose of enhancement, that is, the enhancement of specific traits of human being through scientific and technological means, the optimization of an individual's physical or psychological conditions, and the enhancement of an individual's intellectual and physical abilities, is completely against human dignity and well-being. In such application scenarios, first of all, from the original intention of genome editing, if gene therapy tries to restore the self-determination and self-development potential of the edited person, then gene enhancement is "to impose parental preferences on the enhanced person, and to subdue the autonomy of the en-

23. Zhang Xiaoshan, "Constitutional Limits of Genome Editing in Human Embryos: A Dignity Based Analysis," *Journal of Dalian University of Technology (Social Sciences)* 5 (2020): 114-116.

24. Yu Wei, "Human Genome Editing from the Perspective of Constitutional Law", 194.

25. Liu Yafei, Ma Xiaomin, Sun Hongyan and Wang Yunling, "The Challenge of genome-edited infants to Human Dignity," 35.

26. Yu Houhong, "An Analysis of Rights Conflicts in Human Embryo Genome Editing," *SJTU Law Review* 4 (2021): 88.

hanced person to that of the parents."[27] This could lead to the cases of "genetic selection" and "designer babies." Unlike the cure of disease, the genetic traits preferred by parents may not necessarily be positive under different values and aesthetical criteria. At the same time, parents devalue the infants' lives by imposing their own preferences. The enhanced person is then placed in the position of an object. Reducing individuals simply to their genetic traits is a means to an end for a parent or researcher, no more than customizing an app for preference. This is what the principle of human dignity aims to oppose and prohibit in the first place. In addition, it subverts the traditional parent-child relationship to some extent.[28] Second, from the perspective of the consequences of genome editing, enhancement-oriented genome editing presupposes specific life path choices for the enhanced person. For example, in the movie *GATTACA*, pianists who have been gene edited to have 12 fingers no longer have the right to make their own life plans, and their dignity of autonomy and self-determination cannot be realized, which leads to the distortion of their self-esteem and dignity. Third, the first principle of bioethics is the benefit/no harm principle, which requires that any medical intervention applied to the human body should benefit the recipient more than the harm suffered.[29] Since the purpose of genetic enhancement is not therapeutic, the potential damage to the infant is not necessary to treat the disease, even if the benefit is not effective. Finally, it is highly likely that genetic enhancement will remain only available to a privileged few for a considerable period of time, and that the inequality in using such technologies may lead to discrimination against those without enhancement and exacerbate class divisions. The idea that genetic enhancement can enable individuals to develop morally, intellectually, and socially in a way that is conducive to higher dignity is too idealistic at the current stage. On the one hand, it is difficult to achieve equal access to this technology in the short term, and it is very likely to be monopolized by a few people to enhance the specific capabilities of their future generations. On the other hand, possessing good talents is only one condition for attaining better dignity. The possibility that human beings are inherently good or evil is still open to question, and is not directly related to the ultimate enhancement of human dignity.[30]

Reproductive freedom does not include the right to bear infants beyond their normal state of health, yet that there are cases in which eugenics have been restored in the name of reproductive freedom. The reproductive freedom of the parents does not justify genetic enhancement at the expense of the dignity of the infant. Likewise, the academic freedom of researchers is not without restrictions. Article 51 of China's *Constitution* states that no one shall impair the public interest or the legitimate rights of others in the exercise of their freedoms and rights. The argument that genetic enhancement is a legitimate exercise of the right to academic freedom is obviously un-

27. Yu Wei, "Human Genome Editing from the Perspective of Constitutional Law", 194.

28. Chu Jingyi, "Research on the Legitimacy of genome-edited infants," (Master's Dissertation, China University of Political Science and Law, 2020), 8-11.

29. Han Yuehong, *Human Dignity from the Perspective of Bioethics*, 268.

30. Li Yaming, *Studies on Human Dignity in Bioethics* (Beijing: China Social Sciences Press, 2019), 61-64.

tenable.[31]

The above discussion is based on the premise that there is a clear distinction between treatment and enhancement. However, the distinction between treatment and enhancement is actually subject to considerable scientific and ethical ambiguity, and there are actually a large number of situations in which medical interventions cannot be clearly defined. Among them, the typical situation is: enhancing the body's resistance to avoid any future disease, is the prevention of a possible disease a treatment or an enhancement?[32] The gene-editing infant trial, which aimed to introduce a variant of the CCR5 gene that is immune to HIV, is part of this complex picture. It is believed that serious genetic diseases such as AIDS deprive children of the chance of a normal life from birth compared with other so-called "healthy" people, in which case the absence of HIV infection can be considered "normal bodily function" or "species-typical function." However, the variant CCR5 gene is quite rare. It only naturally exists in 10 percent of Nordic people. Most people still have the wild type CCR5 allele that is susceptible to HIV. Therefore, introducing natural variants that are rare enough into embryos should be considered as enhancement.[33] Meanwhile, the common CCR5 gene protects the body against a range of pathogens, including malaria and West Nile Virus.[34] The modification of the CCR5 gene in infants may reduce the susceptibility to HIV while depriving the infants of a considerable degree of environmental adaptation, which may aggravate the symptoms of patients with WNV infection and increase the mortality rate after influenza infection.[35] This complicates the debate over whether this genome editing is a treatment or an enhancement. In view of this situation, this paper believes that the principle of proportionality should be applied to judge the legitimacy of the purpose of genome editing and the necessity of embryo genome editing methods, such as treatment limited to severe conditions for which no alternative treatment is available. Specific requirements could follow the *Report on Heritable Human Genome Editing* 2020 issued jointly by the National Academy of Medicine, the National Academy of Sciences, and the Royal Society. First, identify circumstances in which the practice of genome-editing therapy is permissible, i.e. the use of human heritable genome editing is limited to severe monogenic diseases (diseases that cause severe morbidity or premature death). The application of this technology is limited to changing the causative gene of a known variant causing the severe monogenic disease to a sequence that is common in the relevant population and known to be non-causative, and to potential parents who (i) have no choice in having a genetically related child without a severe monogenic disease; or (ii) whose options are extremely poor because the proportion of embryos that are expected to be unaffected is unusually low (25 per-

31. Zhang Xiaoshan, "Constitutional Limits of Genome Editing in Human Embryos", 116.

32. Faith Lagay, "Gene Therapy or Genetic Enhancement: Does It Make a Difference?" 3 *AMA Journal of Ethics* 2 (2001): 37.

33. John Novembre, Alison P. Galvani and Montgomery Slatkin, "The Geographic Spread of the CCR5 A32 HIV- Resistance Allele," 3 *PLoS Biology* 11 (2005): 1954.

34. Sunil K. Ahuja and He Weijing, "Double-Edged Genetic Swords and Immunity: Lesson from CCR5 and Beyond," 201 *The Journal of Infectious Diseases* 2 (2010): 171.

35. Christopher Gyngell et al., "The Ethics of Germline Gene Editing", 34 *Journal of Applied Philosophy* 4 (2017): 507.

cent or less), and who have tried at least one cycle of pre-implantation genetic testing and ended with failure. In this way, by defining specific disease types and contexts, the circumstances with the most urgent need for gene therapy can be delineated in terms of health restoration.[36] In addition, much of the public debate on genome editing today is limited to the dichotomy between treatment and enhancement. So there should be more public debate on complex issues in the intermediate areas, such as the compatibility of preventive approaches with the requirements of human dignity.[37] At the same time, ethical studies and interdisciplinary discussion should be deepened to further refine the spectrum between treatment and enhancement from the theoretical level.

C. Specific requirements of the obligation to respect human dignity

As mentioned above, human dignity, as the common objective value order and the highest value norm of the whole legal system, is important not only for the *Constitution* that adjusts the relationship between citizens and the state, but also for the civil law that adjusts the relationship between equal subjects.[38] It is achieved more through the implementation of national obligations.

At the macro level, dignity, as the "intrinsic value of human beings," is the source of legitimacy and the logical premise of all fundamental rights. Through the substantive implementation of human rights, the guarantee of human dignity is realized by ensuring that human beings are respected and protected as they should be and are not insulted or degraded. At the micro level, dignity is a "fundamental human right" or "basic principle of human rights." If the interference with the general rights involves "human dignity," and the general rights are not sufficient to defend against such violations, the principle of "human dignity" can be applied, so that the protection of human rights can be fully extended.[39] Specifically, in the context of genome editing, some of the value elements in the connotations of human dignity can be ascribed to specific rights, including individuals' right to self-determination, right to life, right to the body, right to health, right to privacy and right to freedom from discrimination. In the same vein, bioethical norms also require the practice of genome editing to comply with the principles of informed consent, life first, risk control, privacy protection and equality of life. These will be detailed below.

However, it needs to be explained separately here that the subjective position of "human dignity" cannot be completely covered by other specific rights. As UNESCO's multiple declarations on the human genome and bioethics require, in order to deal with the threat of "subject objectification" brought by genome editing technologies, states should regard human dignity as the highest principle of the development

36. Eli Y. Adashi and I. Glenn Cohen, "Heritable Human Genome Editing: The International Commission Report," 324 *JAMA* 19 (2020): 1941.

37. Derek So et al., "Disease Resistance and the Definition of Genetic Enhancement, Frontiers in Genetics," 8 *Frontiers in Genetics* 40 (2017): 2.

38. Li Haiping, "Criticism of Indirect Effect Theory of Fundamental Rights," *Contemporary Law Review* 4 (2016): 53.

39. Wang Jinwen, "Reflection and Review of the Normative Status of Human Dignity: An Analysis Based on the German Constitutional Doctrine and Judicial Practice," *Chinese Journal of Human Rights* 4 (2021): 79.

of life science and technology, prioritize human well-being and interests over scientific and social interests, and actively avoid the threat to human dignity caused by the development and application of genome editing technologies through various means such as legislation. This is consistent with the basic position adopted by Chinese laws and regulations on human genome editing experiments at the present stage: basic research, preclinical trials or clinical applications of somatic genome editing for medical or research purposes can be carried out; considering the risks in the safety and efficacy of germline genome editing, basic research on germline genome editing is allowed at present, but clinical trials and applications of germline genome editing are prohibited.[40] On this basis, a balance should be struck among the freedom of scientific research, reproductive freedom, citizens' right to health and the principle of respect for human dignity. Genome editing for therapeutic purposes is disease-specific and does not violate human dignity as long as the technology is safe and in accordance with the law. A progressive, dynamic assessment of the feasibility of human genome editing clinical trials and a positive list of diseases that can be treated by genome editing should be insisted on, while we also insist against the pursuit of perfection through gene enhancement.

III. The Right to Physical and Mental Health

The right to physical and mental health is a fundamental human right established by several international human rights conventions or declarations. Paragraph 1, Article 12 of the *International Covenant on Economic, Social and Cultural Rights* defines the right to health as "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health." Paragraph 2 of the same article sets out a number of obligations of states parties. The *General Comment No. 14 of the UN Committee on Economic, Social and Cultural Rights* further clarified that the right to physical and mental health is a broad concept that can be subdivided into more specific rights. Closely related to this paper are the right not to be subjected to forced testing without consent, that is, the implementation of the principle of informed consent, and the freedom to be physically intact and the freedom from harmful practice. Among China's domestic laws, although the *Constitution* does not stipulate the right to physical and mental health in the chapter of "Fundamental rights and obligations of citizens," Articles 21, 26, 36, 37 and 45 of the *Constitution* guarantee the rights and interests of the body in terms of the development of medical and health services, environmental protection, prohibition of damage, personal freedom and the obligation of the state to provide assistance. Article 33, the "human rights clause," can also serve as a basis for this right. In the chapter of "Right to life, right to body and right to health" of the Book on Personality Rights, the *Civil Code* stipulates the three kinds of material personality rights, requiring the protection of the safety of life, the dignity of life, the integrity of body, the freedom of movement and physical and mental health in the narrow sense of natural persons.

Based on the theory and practice of international human rights law, this paper

40. Wang Kang, "Legal Liability in Human Trials of 'genome-edited infants': A Hermeneutic Analysis Based on China's Current Legal Framework," *Journal of Chongqing University (Social Science Edition)* 5 (2019): 135.

divides the right to informed consent into three parts. Among them, the principle of informed consent aims to guarantee the freedom of movement (or self-determination) of individuals, the right to one's body corresponds to the integrity of the body protected by international law, and the right to health corresponds to the protection from harmful practice. The subjects or entities shouldering human rights obligations at this stage include researchers, sponsors and ethics committees. At the same time, the state shall, through legislation and other measures, prevent the aforementioned third parties from interfering with or violating the right to health.

A. The principle of informed consent

The principle of informed consent for human experimentation has been gradually established as one of the principles of medical ethics and research ethics since the trial of Nazi doctors in Nuremberg. The Nuremberg trials revealed that Nazi doctors carried out mandatory and inhumane human experiments on subjects, and the international community began to pay attention to ethical norms in medical activities. "Because the biomedical research that human subjects participate in involves their right to life, health, body, privacy, treatment, compensation, etc., an important way to respect and safeguard these rights is to obtain their informed consent, which is also the most basic and core right."[41] Thus, in the *Nuremberg Code* adopted after the trial provides that "The voluntary consent of the human subject is absolutely essential. The person involved should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him/her to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him/her the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his/her health or person, which may possibly come from his/her participation in the experiment." The *Declaration of Helsinki* adopted by the 18th General Assembly of the World Medical Association in 1964 clearly defined "voluntary consent" as "informed consent," expanded the content of rights, and extended the principle of informed consent from the research field to the medical field. Article 3 of the 2000 *Charter of Fundamental Rights of the European Union* includes the right to informed consent under the right to integrity of the person. At the same time, it should be pointed out that, as mentioned above, the establishment of this principle is closely related to the bitter lessons of World War II. In view of the fact that the Nazi authorities had forced certain individuals to undergo specific medical experiments, the emphasis on "voluntary consent to medical or scientific experimentation" was based on the requirement of the fundamental human right to freedom from torture. According to the definition of "torture" in Article 1 (1) of the *Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or*

41. Zhao Luping and Wu Zhi'ang, "Status Quo and Improvement Measures of Informed Consent of Clinical Research Subjects in China," *China Pharmacy* 41 (2014): 3844.

Punishment adopted by the UN General Assembly in 1984, torture does not cover private acts. But paragraph 2 of the *UN Human Rights Council's General Comment No. 20* adopted in 1992 stipulates clearly that "It is the duty of the State Party to afford everyone protection through legislative and other measures as may be necessary against the acts prohibited by Article 7, whether inflicted by people acting in their official capacity, outside their official capacity or in a private capacity." It is also emphasized in paragraph 5 that "Article 7 of the *International Covenant on Civil and Political Rights* protects, in particular, children, pupils and patients in teaching and medical institutions." Paragraph 7 specifically emphasizes the importance of free consent of individuals for the conduct of medical or scientific experiments, as well as the special protection that should be granted when subjects are unable to give valid consent or are in detention or imprisonment. Under the article "the right to freedom from torture," as a State Party to the *International Covenant on Civil and Political Rights*, China should inform the Human Rights Committee of the legislative, administrative, judicial and other measures it has taken to prevent and punish human genome editing experiments carried out without the free consent of the individuals concerned. The rights of victims of abuse to complain, to receive compensation and to rehabilitate as much as possible should be fully guaranteed.

At present, the basic status of informed consent has been emphasized in the medical field in China, which includes the right to be informed and the right to consent. According to China's current law, the obligations of researchers in gene-editing clinical trials can be summarized as follows. First, regarding the timing of notification, researchers should inform subjects before screening for clinical trials. The researchers also have the obligation to provide timely and dynamic information on the progress of the trial during its course, especially when the risk profile changes. For example, if some subjects have serious adverse reactions, they should inform other subjects and let them decide whether to continue to participate in the trial or withdraw. Second, in terms of information, the researchers should fully explain the clinical trial situation of the subject, especially the factors that may influence the decision made by the subject. In addition to the conventional information, such as the purpose of the trial, process of the trial, privacy and confidentiality, risks and benefits, the right of the subject to withdraw at any time, and the compensation available to the subject, particular attention should be given to the full description of potential risks in genome editing experiments, alternative drugs or treatment options, and possible lifelong monitoring or long-term follow-up.[42] Third, in terms of the way of informing, the researchers should truthfully and appropriately explain the clinical trial to the subjects. Researchers should truthfully inform subjects about the clinical trials, avoid unreasonable deception or concealment of relevant information, and should not use inducement, coercion or other improper methods to influence decisions made by the subject. For specific compliance practices, we can refer to the accreditation method in the 2016 International Ethical Guidelines for Health-related Research Involving Humans. Circumstances such as mental illness, dependent relationship, severe disease or poverty

42. Erica C. Jonlin, "Informed Consent for Human Embryo Genome Editing," 14 *Stem Cell Reports* 4 (2020): 534.

may threaten the voluntariness of subjects. In these cases, research ethics committees must determine for each individual protocol if influences on voluntary consent cross the threshold of being undue, and if so, which safeguards are appropriate. In principle, under the circumstance of a dependent relationship between the subject and researcher, a neutral third party should obtain informed consent. However, in some situations of dependency, it is preferable that the clinician provide the patient with information since he or she is most knowledgeable about the condition of the patient. However, to minimize the influence of the dependent relationship, several protective measures must be taken.[43] In addition, researchers should take appropriate measures to inform subjects about clinical trials. These efforts include: both oral and written materials should be in plain, clear and accurate language; researchers should fully consider personal factors such as living conditions and education level of potential subjects; the recipient of informed consent should know enough about the research to be able to answer any questions from potential subjects; and potential subjects should be given adequate time and resources to consider participation, including consultation with family members.[44] Fourth, for the eligible subject who is informed, if the subject does not have full capacity for civil conduct, the researchers should not only obtain the consent of the guardian of the subject, but also provide sufficient information about the study according to the ability of the subject to understand the information, and obtain the consent of the subject as much as possible. For example, when using children as subjects, researchers should provide enough research information tailored to the child or adolescent's intelligence and understanding ability, obtain consent consistent with the child or adolescent's ability, and their objections should also be respected.[45]

In addition, the sponsor and the ethics committee also have corresponding obligations. As the initiating subject, managing and providing funds for clinical trials, the sponsor is responsible for ensuring the researchers obtain informed consent. A quality management system for clinical trials should be established to manage risks in the process of informed consent. Besides, the time and manner of informed consent should be monitored to ensure that the researchers have fulfilled the obligation of informed consent and obtained the consent of the subject by signing the informed consent form before the clinical trial.[46] The ethics committee should review whether the information provided in the informed consent is complete and easy to understand, focus on the waiver clause and supplementary clause in the informed consent,[47] as well as check whether the process by which researchers obtained informed consent was compliant and appropriate.

As for the requirement of informed consent in germline gene editing, in fact, the subjects at the moment are embryos that are obviously not eligible givers of informed

43. Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO), *International Ethical Guidelines for Health-related Research Involving Humans (2016)*, translated by Zhu Wei, edited by Hu Qingli (Shanghai: Shanghai Jiaotong University Press, 2019), 34-35.

44. Ibid., 33.

45. Ibid., 65-69.

46. Chapter 5 of Quality Management Specifications for Pharmaceutical Clinical Trials (2020).

47. Ibid., Art. 12 (4), (7).

consent. So one of the most important and controversial issues is the "legitimacy of intergenerational consent," which is about "intergenerational justice" — whether the "parents" are eligible to exercise informed consent on the basis of genetic screening and expert opinion on behalf of early human embryos (their future "children") and make a decision about some kind of genome editing that affects their life status.[48]

The academic world has not settled on an answer to this question. The existing view is similar to a spectrum. At one end of the spectrum, is the view parents' intergenerational consent for genome-edited infants deprives the child of the opportunity to be the "sole author of his or her life," which is serious violation of the ethical principle of self-determination and therefore unacceptable.[49] On a policy level, the National Institutes of Health (NIH) also prohibits funding such embryonic genome editing research on the grounds that it "affects future generations by editing germline genes without their consent."[50] Next to that is the view that intergenerational consent should be accepted only in very exceptional circumstances, such as when a particular human embryo suffers from a serious genetic defect.[51] Next along the spectrum, is the view that believes that "the parents of the subjects have the ability of informed consent in a general sense and can make reasonable judgments about the consequences of their choices. Therefore, they can also follow the practice of children participating in clinical trials of new drugs to obtain the qualification of attorney consent." However, in order to protect the interests of genome-edited infants, the informed consent of the parents of the subjects should be fully guaranteed on the part of their "right to informed consent." At the same time, attorney consent should follow certain principles, such as "the ability and scope of future children to make life choices as adults should not be deliberately limited."[52] At the other end of the spectrum, the relatively more extreme view that "based on parental rights, parents are allowed to shape their children at least when they are minors or very young. This freedom and authority of parents will extend to genome editing technologies, thereby giving them the freedom to edit genes without government interference." Intergenerational consent should be recognized as long as the parents do not harm the vital interests of the child.[53]

From a legal point of view, given that parents are generally presumed to act in the best interests of their children, when a parent makes a medical-related decision for their child, even if the decision does not fully comply with current medical standards,

48. Li Jianjun and Wang Tian, "The Ethical Debate Caused by Human Embryo Genome Editing Research," *Science and Society* 3 (2016): 36-37.

49. Jürgen Habennas, *The Future of Human Nature* (Cambridge: Polity Press, 2003), 59. Jonathan Pugh, "Autonomy, Natality and Freedom: A Liberal Re-examination of Habermas in the Enhancement Debate," 29 *Bioethics* 3 (2015): 148.

50. Francis S. Collins, "Statement on NIH funding of research using genome-editing technologies in human embry- os," in *National Institutes of Health*, accessed February 13, 2022, http://www.nih.gov/about/director/04292015_statement_gene_editing_techn-ologie-s. htm.

51. Li Jianjun and Wang Tian, "The Ethical Debate Caused by Human Embryo Genome Editing Research", 37.

52. Wenfeng Tian and Xinqing Zhang, "Surrogate Consent Problem in genome-edited infants," *Science and Society* 2 (2019): 21; Naomi Cahn, "CRISPR Parents and Informed Consent," 23 *SMU Science & Technology Law Review* 3 (2020): 16-17.

53. Ma Chi, "The Rights Basis of Human Genome Editing," *ECUPL Journal* 5 (2019): 46-59.

the law generally respects the decision. Intervention generally only happens in cases of parental abuse or neglect of the child.[54] Legislation that allows close relatives of patients to give informed consent under certain circumstances also reflects such a value orientation. However, on the basis of fully guaranteeing parents' informed consent, how to construct rules to fully protect the rights and interests of offspring and prevent parents from abusing their rights and violating public interests have become the key issues to be solved.

Regarding the informed consent required for germline genome editing in clinical trials, because it involves the protection of the rights of future generations, it has compliance requirements necessary for general forms such as medicines, medical apparatus and life sciences and medical research involving people. For example, the language description of informed consent shall be easy to understand and expressed in a friendly manner so that the subject or guardian, attorney, or witness can easily understand. The informed consent shall not contain any content that will cause the subject to give up the legal rights and interests and exempt the institution, principal researcher, and sponsor of the clinical trial of the medical equipment from responsibility. In addition, it is still necessary to comply with the relevant special provisions of APPENDIX 2 (ethical review of research in genetics and reproductive medicine) and APPENDIX 6 (ethical review of stem cell clinical research) of the *International Ethical Guidelines for Health-related Research Involving Humans*. They include: first, the provisions in "key points of ethical review of clinical genetics research" on informed consent require research institutions and medical institutions to inform in writing that they will take confidentiality measures for the collected genetic data and information. "The subject shall be informed in detail of the purpose of the collection of genetic data, the method of collection (including interventional or non-interventional methods), the processing (anonymization) of the data, the use and storage of the data. The use of data must not exceed the scope of informed consent."[55] Second, the regulation of "ethical review of stem cell clinical research" on risk disclosure requires that "researchers, clinicians and medical institutions should allow subjects to exercise effective informed consent when they have sufficient decision-making ability. Subjects should be provided with precise information about the risks of stem cell innovative therapies and the current status of stem cell innovative therapies in both scientific and medical contexts."[56] From the perspective of interpretation, it should include the following content. Research institutions and medical institutions must provide ethical review data to the subjects and provide explanations to prove that the research institutions are qualified for genome editing research and experiment. It is forbidden to exaggerate the possible benefits of genome editing, and to conceal or underestimate the discomfort and risks that this operation may bring. They should fully inform the existing treatment, insufficiency of the existing drugs, the results of the preliminary study of experimental drugs, alternative research methods of the target disease. Third, on the

54. Naomi Cahn, "CRISPR Parents and Informed Consent", 9-21.

55. Office of Medical Ethics Expert Committee of NHC and Chinese Hospital Association, *Guidelines for the Construction of Ethical Review Committees for Clinical Research Involving People (2020)*, page 45.

56. Ibid., 61.

"minimum risk" and "risk benefit assessment," the "ethical review of stem cell clinical research" provides that "If the subject lacks decision-making capacity, legal guardian's attorney consent should be used, and the subject should be strictly protected from increasing the risk of non-therapeutic procedures beyond the minimum risk. When an intervention is tested on subjects who lack informed consent, risks arising from the course of the research should be limited to minimal risks unless the associated therapeutic benefits greatly outweigh the risks. With the attorney consent of the legal guardian, if there is a significant risk of a change in the risk/benefit ratio in the course of a clinical study of cellular intervention or an alternative therapy study, the informed consent of the legal guardian must be re-obtained."[57] In practice, medical institutions and research institutions should fully demonstrate the potential benefits of treatment for potential participants in the embryonic state, which requires the provision of genetic diagnosis and proof of genetic defects in embryos, i.e. objective medical needs, as well as the priority of germline genome editing as the preferred treatment. At the same time, medical and research institutions should timely inform parents of possible risks, including the possibility of off-target, miscarriage due to ineffective editing, or morbidity after birth, according to the specific situation of the trial. And parents have the right to withdraw from the trial unconditionally at any time.

In addition, China may consider drawing lessons from international experience when working on legislation to fully implement the human rights obligation to protect the right to health. For example, according to the *International Ethical Guidelines for Health-related Research Involving Humans (2016)*, which guides global health research, when pregnant women are included in a study, "Researchers and research ethics committees must ensure that potential research participants are adequately informed about the risks to breastfeeding women and their infants, and about the risks to pregnant women (including future fertility), their pregnancies, their fetuses, and their future offspring. The information must also include steps to maximize potential individual benefits and minimize risks. When evidence concerning risks is unknown or conflicting, this must be disclosed to the pregnant or breastfeeding woman as part of the informed consent process. She is the one to finally decide the acceptability of these risks to her and her fetus or infant. Women must also be informed that it is often difficult to determine causality in fetal or infant abnormalities cases."[58] US law also requires that pregnant women meet additional requirements for research participation.[59] For example, in cases where the research is beneficial only to the genome-edited infant, consent from the father is required, and the informed consent needs to indicate reasonably foreseeable effects of the research on the genome-edited infant.

B. The right to bodily integrity

The application of human genome editing technologies involves the insertion, deletion, modification or replacement of DNA in the living genome, thus changing the

57. Ibid., 62.

58. Council for International Organizations of Medical Sciences (CIOMS) and World Health Organization (WHO), *International Ethical Guidelines for Health-related Research Involving Humans (2016)*, 74.

59. 45 C. F. R. § 46. 204 (2019).

characteristics of the body, which inevitably leads to damage to the integrity of human genetic information. But health considerations can sometimes take precedence over bodily integrity, that is, the external integrity of the human body may be sacrificed to a certain extent in order to maintain the proper functioning of the body's internal mechanisms,[60] such as amputation of limbs in the case of gangrene. Because the current genome editing technologies are not mature, although the uncertainty and irreversibility of the technical risk have been reduced, the risk coefficient of harm to human health of the technologies is still high. For example, situations that may cause genetic mosaics and off-target effects and have potential adverse effects on the health of the subject shall not be approved by the relevant competent authorities and reviewed and approved by the ethics committee. After the subsequent technical risks have been reduced to an acceptable level, if medical and scientific activities related to human genome editing threaten the integrity of the body, but contribute to the healthy operation of the body, then they may be implemented on the premise of proportionality assessment, and being approved by the relevant competent authorities and examined by the ethics committee.

In the genetic testing of human embryos, the right to bodily integrity of the person mainly involves the use of embryos and the disposal of surplus embryos, including leftover embryos that met the experimental criteria, embryos that were "sifted out" and those that were forgotten.[61] Considering that the embryo, as an early form of life, has the potential to develop into an adult, it should be treated in a manner consistent with human dignity. First, according to Article 1007 of the *Civil Code*, selling and buying human organs and tissues such as gametes, fertilized eggs and human embryos in any form is strictly prohibited in order to safeguard human dignity. Second, when selecting subjects for experiments, the use of embryos should be avoided if they can be replaced by other subjects, such as embryonic stem cells. Third, the principle of minimum impact should be adhered to when embryos are bred. At the time of research approval, the experiment should be designed to achieve the research objective using the minimum number of embryos to avoid redundant frozen embryos and increase the management cost or the ethical controversy caused by discarding the remaining embryos. Fourth, the approval for experiments must be based on the scientific verification of basic research. For example, it is required that the safety and efficacy of somatic gene therapy have been verified on a large scale in clinical studies and that these gene interventions have established safe and reliable animal models. Fifth, when carrying out embryo experiments, the review and approval of the ethics committee should be necessary. On the one hand, it is beneficial to protect the rights and interests of embryo donors from infringement. And on the other hand, it is necessary to ensure that experiments are conducted for the purpose of medical and scientific research rather than to pursue commercial value. Otherwise, it is objectifying "human beings" and violating ethics. In addition, in combination with the above requirements, the principle

60. Zhu Xiaofeng, "The Legal Limits and Obligations of Freedom to Human Genome Editing Research," *Wuhan University Journal (Philosophy & Social Science)* 4 (2019): 25.

61. Wang Kang, "Legal Regulation of Human Genome Editing Experiments: A Discussion on the Legal Issues of Gene Diagnosis Before Embryo Implantation," *Oriental Law* 1 (2019): 12.

of informed consent should be adhered to during embryo disposal. For example, when hospitals sign informed consent forms with patients undergoing artificially assisted reproduction, it is necessary to explain whether the remaining embryos can be donated for scientific research and clearly inform patients of the known research information.

C. The right to health

As the *Declaration of Helsinki* states, "In medical practice and in medical research, most interventions involve risks and burdens." The principle of informed consent enables potential subjects to have a correct understanding of the risks and burdens to be borne by participating in or continuing the trial. Therefore, the design and conduct of the trial should adhere to the principles of life first and risk control, so as to avoid any damage to the physical health of subjects beyond the scope of legal permission.

In this regard, clinical researchers have the primary responsibility for the protection of subjects' right to health. The principles of life first and risk control require that research should be conducted in a responsible manner by competent researchers. The obligation requirements include: first, the obligation to control risks. At the time of protocol design, medical trials should be conducted only if the importance of the research purpose outweighs the health risks and other burdens borne by the subjects. However, this does not mean that the scientific and social interests take precedence over the personal safety and right to health of the subjects, but that the researchers have fully evaluated and properly managed the relevant risks, and are able to minimize the risks and burdens borne by the subjects. Although the medical and scientific activities related to human genome editing often involve important scientific value, under no circumstances should the subject's rights to the body and health of the subjects in the current research be ignored in order to obtain more clinical scientific knowledge and for the health benefit of the majority of future patients.[62] Specifically, first of all, the safety and efficacy of gene therapy should be verified on a large scale in clinical practice. This requires these gene interventions gradually go through the complete progressive transformation process of basic research and preclinical research, enter clinical research or clinical application, and meet the safety standards and effectiveness standards at each stage.[63] Besides, researchers should fully estimate the possible risks and burdens of the research for the subjects and related individuals, including but not limited to health risks, and compare the potential benefits of the research for the researchers and other related groups. Finally, a reasonable management approach that minimizes risk and contingency plans for particular circumstances should be provided when concluding that research can be carried out. Second, the obligation of legal qualifications and procedures. The researcher and the clinical trial institution shall have the appropriate qualifications and meet the corresponding requirements, including

62. Office of Medical Ethics Expert Committee of NHC and Chinese Hospital Association, *Guidelines for the Construction of Ethical Review Committees for Clinical Research Involving People (2020)*, Part I Preface.

63. Han Yuehong, "The Moral Boundary of Innovation: Reflection on the Ethical Regulation in the genome-editing Infant Incident," *Journal of Kunming University of Science and Technology (Social Sciences)* 2 (2019): 31.

but not limited to the researcher having the practice qualification in the clinical trial institution and being able to give proper medical treatment to the subject.[64] In the case of germline genome editing, qualification for the use of human assisted reproductive technologies is also required, as well as the approval of the ethics committee. Third, the obligation of implementing the research protocol. Once the experiment is initiated, the researcher shall comply with the protocol approved by the ethics committee and shall not modify or deviate from the protocol without consent. Risks should be continuously monitored, assessed, and documented by the researcher.[65] The protocol should be reevaluated when it is found that the expected risks exceed the potential benefits, when the project is not completed but critical evidence has been obtained that points to a clear conclusion, or when the results have been obtained by other research teams.[66] Fourth, the obligation of timely treatment. In case of adverse reactions, sufficient attention should be paid to the abnormal symptoms of the subject, diagnosis and treatment suggestions should be provided, and necessary measures should be taken for timely treatment.[67]

As provider of drugs or medical apparatus and instruments, the sponsor has guarantee obligations, supervision obligations and compensation obligations. First, the safety of the experimental drug or medical apparatus and instruments should be guaranteed. The sponsor shall immediately notify all related institutions and researchers of any potential impact on the safety of the subjects or situations that may alter the ethics committee's approval for the continuation of the trial and act accordingly.[68] Second, all researchers conducting clinical trials should be supervised to ensure that they strictly follow the laws, regulations and clinical trial protocols.[69] Third, the sponsor shall bear the treatment expenses and corresponding economic compensation for the subjects who suffer from injury or death related to the clinical trial, except for the damage caused by the fault of the medical institution and its staff during the diagnosis and treatment activities. Related to this, the sponsor shall purchase insurance to compensate subjects for clinical experiment-related damages during the experiment.[70] When a trial is submitted to an ethics committee for review, the ethics committee should focus on "whether the risks to which the subject is likely to be exposed are reasonable concerning the expected benefits of the study" and "whether there are preventive and response measures to the risks to which the subject may be exposed in the study."[71]

64. Article 61-64 of *Quality Control Specification for Clinical Trials of Medical Equipment*; Article 16-18 of *Quality Control Specification for Clinical Trials of Drugs*.

65. Article 66 of *Quality Control Specification for Clinical Trials of Medical Equipment*; Article 20 of *Quality Control Specification for Clinical Trials of Drugs*.

66. World Medical Association: *Declaration of Helsinki — Ethical Principles for Medical Research Involving Human Subjects*, Articles 17-18; Article 76 of *Quality Control Specification for Clinical Trials of Medical Equipment*.

67. Article 69-72 of *Quality Control Specification for Clinical Trials of Medical Equipment*; Article 18, Paragraph 1 (2) of the *Quality Control Specification for Clinical Trials of Drugs*.

68. Article 45 of *Quality Control Specification for Clinical Trials of Medical Equipment*.

69. Ibid., Art. 47.

70. Ibid., Art. 48.

71. Article 20 of the *Ethical Review Measures for Biomedical Research Involving Human Beings*.

At the same time, the right to health, as a fundamental human right, also requires states to undertake the obligation of protection. Taking into account the provisions of the *International Covenant on Economic, Social and Cultural Rights* and the *General Comment No. 14 (2000)* of the Committee on Economic, Social and Cultural Rights on the highest attainable standard of health, states parties have an obligation to ensure the right to health without discrimination, which requires special care for vulnerable and marginalized groups to achieve substantial equality. What needs to be emphasized here is the protection of the right to health of infants who have undergone germline genome editing. Such infants have multiple characteristics of vulnerability. They are not only born into HIV-infected families, but also face special uncertain health risks and may be affected by stigma and discrimination, and belong to a group deserving special protection. In this context, there is no doubt that He Jiankui and his team should bear the corresponding tort liability for the health monitoring and disease treatment that may be needed. However, in the case that He is unable to pay the corresponding compensation or the elements of tort liability are difficult to prove, the state should take the obligation of diagnosis, treatment and rescue. At the same time, genome-edited infants may not complete self-identity and self-acceptance, and long-term health monitoring may cause self-doubt. So the state also needs to provide appropriate psychological counseling and comfort through corresponding institutional measures to maintain their mental health, and realize the complete guarantee of right to health.

Generally speaking, it should be noted that the protection of the right to health has a certain particularity in genome editing. First, in this case, it is necessary to emphasize the protection and realization of the informed consent of the rights subjects, that is, to fully protect their front-end autonomous decision-making rights, to effectively avoid the infringement of their right to health. Second, since the primary research object of genome editing is exceptional, which is an embryo with the potential to become a human life, the utilization of specific embryos and disposal of the remaining embryos need special treatment, which constitutes the particular requirement of body integrity and inviolability. Finally, the genome editing scenarios raise further demands for human rights protection. To effectively protect the right to the health of genome-editing clinical trial subjects, states should not only fulfill their obligation to protect the right to health from infringement by third parties, but more importantly, take active measures to provide special protection to particularly vulnerable groups, such as genome-edited infants. These more specific protection measures will allow the right to health of this particularly vulnerable group to be properly realized.

IV. Right to Privacy and the Protection of Individual Information

If the right to physical and mental health discussed above is the fundamental premise for maintaining individual survival, the rights to privacy and personal information are the basis for ensuring individuals' establish their identity in society and the free development of their personality. Regarding the purposes of protection, there is a difference between protecting the privacy and personal information. Because privacy is about concealment and leaving someone alone, it is more about avoiding the

illegal attention or intervention of others. Personal information, on the other hand, is a product of the digital age, which emphasizes the right of individuals to self-determination over their identity information, and prohibits illegal acquisition, processing or disclosure by others. In the scenario of genome editing, part of the information, such as health information and gene information, constitutes both privacy and sensitive personal information, which involves the protection of privacy and personal information.[72] But because of the different purposes of right protection, different protection requirements are put forward.

A. Right to privacy

The right to privacy is directly and clearly defined in international human rights law. Article 12 of the 1948 UN *Universal Declaration of Human Rights*, the first document of international law to stipulate the right to privacy, states that "No one shall be subjected to arbitrary interference with the privacy, family, home or correspondence, nor to attacks upon the honour and reputation. Everyone has the right to the protection of the law against such interference or attacks," After that, the right to privacy is also provided for in Article 8 of the 1950 *European Convention on Human Rights* and Article 17 of the 1966 UN *International Covenant on Civil and Political Rights*. The UN Human Rights Committee has made this clear in its General Comment No. 16 that the right to privacy is protected against "all interference and attacks, whether from state authorities or from natural or legal persons." Article 7 of the *EU Charter of Fundamental Rights* in 2000 also stipulates the right to privacy, including the right to respect for private life, family life, home and correspondence.

Privacy is not only an international human right but also a fundamental and civil right. Although there is no universally applicable independent privacy clause in China's *Constitution*, the protection of this right is not absent. The "human rights clause" of Article 33 (3) of the *Constitution* may serve as a normative basis for "unenumerated fundamental rights." At the same time, due to the personality attribute of privacy, the "personal dignity" clause in Article 38 of the *Constitution* can also be used as the normative basis of the right to privacy. Together, these two clauses may constitute the normative source of a general constitutional right to privacy. Article 39 of the *Constitution* protects the privacy of the house, and Article 40 of freedom of communication and privacy of communication separately protects the privacy of private space and private information.[73] Chapter 6 of Part IV (Personality Rights) of the *Civil Code* of China specially stipulates the right to privacy and the protection of personal information, establishing the right to privacy as a personality right parallel to other fundamental rights, such as the right to life, health, and reputation. Article 1032 defines the right to privacy — "Privacy is the undisturbed private life of a natural person and his private space, private activities, and private information that he does not want to be known to others." Article 1033 clearly defines the types of acts that infringe on the

72. Wang Liming, "Basic Issues of Sensitive Personal Information Protection: Based on the Interpretation of the Civil Code and the China Personal Information Protection Law," *Contemporary Law Review* 1 (2022): 6-7.

73. Li Zhongxia, "Constitutional Construction of Privacy Rights in the Digital Era," *ECUPL Journal* 3 (2021): 49.

right to privacy and promotes a "binary system" of privacy and personal information protection. For the overlapping parts, Para.3 of Article 1034 provides the path of applying the law: "For the confidential information included in personal information, the provisions on privacy rights shall apply; if no provisions are available, the provisions on personal information protection shall apply."

"The essence of the right to privacy lies in the 'right to be different' of the right holder to maintain his/her individual characteristics, and its legislative purpose is to ensure that the individual has the right to decide on his/her private affairs and exclude the unreasonable attention or intervention of others."[74] In the scenario of genome editing, the private information of biological sample providers and subjects should be particularly protected, that is, the information that can be identified to a specific natural person, or the information that is not intended to be known by others, and has nothing to do with the public interest and the interests of others,[75] such as having received operation of genome editing. Privacy protection rules apply to the protection of private information. First, according to Article 1033 (5) of the *Civil Code*, "explicit consent" should be obtained from the person from whom private information is to be processed or by law. Otherwise, any organization or individual's handling of other people's confidential information constitutes an infringement of privacy rights. Combined with the above analysis of the principle of informed consent, explicit consent means, first and foremost, that the relevant institution and its staff, such as researchers in genome-editing clinical trials, should be fully informed of the specific content, purpose, use, and manner of use of the information collected. Moreover, it means that the person with the right to privacy should, based on complete understanding and voluntary provision, make an individual expression of intention for the processing of private information. Second, according to Article 1032 of the *Civil Code*, no organization or individual may infringe upon the other's right to privacy by prying into, intruding upon, disclosing, or publicizing other's private matters. Article 1039 emphasizes the obligation of confidentiality imposed on subjects of public law — "State organs and the chartered institutions assuming administrative functions as well as their staff shall keep confidential the privacy and the personal information of natural persons known to them during the performance of their responsibilities, and shall not disclose or illegally provide it to others." This requires the front-end researchers and sponsors to keep personal biometric information confidential and pay attention to avoid illegal or unauthorized access, disclosure, dissemination, modification, damage, and loss of information in processing clinical trial information and subject information. It is also required that other people in the middle-end who know the privacy information in the testing, treatment, rescue, and other links, such as government staff, should do an excellent job in the confidentiality of each link. The uninformed public at the back end should avoid actively probing, intruding and interfering with the privacy of biological sample

74. Shi Jiayou, "Reflection on the Relationship between Privacy Rights and Personal Information," *Journal of Shanghai University of Political Science and Law (The Rule of Law Forum)* 5 (2021): 81.

75. Zhang Lu, "What is Private Information?: A Discussion on the Overlapping Parts of Privacy Rights and Personal Information Protection Based on the Civil Code," *Journal of Gansu University of Political Science and Law* 1 (2021): 86-100.

providers and subjects. The ethics committee shall ensure that the research project has adequate measures to protect the privacy of the subjects and maintain the confidentiality of the personal information of the subjects. When the personal health information of the subject is used for the health needs of the subject, scientific research, and major public interests, it must be effectively authorized by the ethics committee, and the collected information should be de-identified. In addition, private information such as the birth history of genome-edited infants should be strictly protected, especially from the staff of relevant authorities. It is obvious that such private information, once leaked, will cause the genome-edited infants to suffer significant discrimination and seriously affect their personality development. According to Article 1039 of the *Civil Code*, "State organs and the chartered institutions assuming administrative functions as well as their staff shall keep confidential the privacy and the personal information of natural persons known to them during the performance of their responsibilities, and shall not disclose or illegally provide it to others." Therefore, in the event of leakage, the relevant personnel should bear corresponding civil, administrative, and party discipline responsibilities.

B. Protection of individual information

The right to personal information is also a fundamental human right under international law. The *Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data* adopted by the European Council in 1981 is the first international convention to provide for the protection of personal information. Under its direct influence, the European Union adopted the *Directive 95/46 on the protection of individuals with regard to the processing of personal data and on the free movement of such data* in 1995, comprehensively stipulating the relevant system for the protection of personal information. The 2000 *EU Charter of Fundamental Rights* is a landmark document in particular. Article 8 of the Charter separately recognizes the protection of personal data as a fundamental right, in addition to the right to privacy (Article 7). Article 8 provides that "1. Everyone has the right to the protection of personal data concerning him or her. 2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified. 3. Compliance with these rules shall be subject to control by an independent authority."

According to the basic theory of personal information protection, personal information can be further divided into general personal information and sensitive personal information according to the possible harmful consequences of illegal information processing. Sensitive personal information refers to "personal information that, once leaked or abused, can easily endanger the safety of person and property or cause damage to personal dignity or discriminatory treatment," including health information, genetic information, biometric information, etc.[76] Based on the general provisions of the personal information processing rules, the *Personal Information Protection Law*

76. Hu Wentao, "Conception on the Definition of China's Personal Sensitive Information," *China Legal Science* 5 (2018): 252.

particularly provided for the "*Rules for Processing Sensitive Personal Information*" in Section II of Chapter II. This section defines the scope of sensitive personal information, including biometrics, medical, and health information, stipulates the preconditions and necessary conditions for processing sensitive personal information, as well as the obligations of individual information handlers, and strengthens the protection of minors' personal information. Although personal biometric information is not clearly defined in the *Personal Information Protection Law*, according to the provisions of the Personal Information Security Regulations, common personal biometric information includes genes, fingerprints, voice prints, palm prints, iris and facial recognition features, etc. The gene information involved in genome editing belongs to personal biometric information, which should be given special protection as sensitive information. Some international laws have made direct provisions for biometric information in genome editing. Article 14 of the *International Declaration on Human Genetic Data* clarifies that "The privacy of an individual participating in a study using human genetic data, human proteomic data or biological samples should be protected, and the data should be treated as confidential." Article 9 of the *Universal Declaration on Bioethics and Human Rights* has similar expressions.

Different from privacy, the purpose of the personal information protection system is to maintain the control and decision of individuals over their identity information. The legislative purpose of the *Personal Information Protection Law* is to ensure the transparency of the information processing process to a large extent. Moreover, personal information has the dual value of dignity and resource. The *Personal Information Protection Law* also takes "promoting the rational use of personal information" as one of the legislative purposes, so the protection rules of personal information are different. From the particularity of biometric information as sensitive information, first, regarding the rights to control and decision-making of the information subject, the *Personal Information Protection Law* requires that the handling of sensitive information should be based on the individual consent of the information subject. Meanwhile, it also stipulates the general and additional information that should be informed to individuals when handling sensitive personal information, including the necessity of handling sensitive personal information and the impact on personal rights and interests. Second, regarding information processing activities, the *Personal Information Protection Law* requires a specific purpose, sufficient necessity, and strict protective measures to handle sensitive personal information. The "specific purpose" requirement is of a higher standard than the "clear and reasonable purpose" set out in Article 6 of the *Personal Information Protection Law*. It should refer to a specific and defined purpose. For example, if a processor processes the biometric information of a genome-edited infant for the purpose of routine health monitoring, the processor shall not use such sensitive personal information for processing purposes unrelated to health monitoring, such as medical research. On the "sufficient necessity" requirement, the *Civil Code* and *Cybersecurity Law* have put forward the principle requirements of being "legitimate, legal, and necessary" for personal information processing. However, neither law further explains or clarifies the "sufficient necessity" in handling sensitive personal information. Therefore, the principle of proportionality can be introduced.

In this case, necessity can be interpreted as: when handling sensitive personal information, it shall be limited to collecting the least personal information necessary to achieve a specific processing purpose and processing in a manner that has the least impact on the individual. For example, in the context of monitoring the health of genome-edited infants, the gene sequence of the edited gene and the health indications of the diseases treated by genome editing are all necessary information. But the information on whether the genome-edited infants had or were at risk for other congenital diseases, such as Huntington's disease or thalassemia, should not be collected, analyzed, and tracked by medical institutions because it is not directly related to the follow-up of genome editing, though it is also reflected in genetic information. The requirement of "strict protection measures" means that compared with the processing of general personal information, more adequate protection measures should be taken for sensitive individuals to ensure the security of sensitive personal information processed. For example, biobanks and sample users jointly sign a confidentiality commitment of biological samples and information donors. Medical institutions should limit the personnel who can access sensitive personal information as much as possible. In addition, considering that the biometric information of individuals undergoing genome editing has great resource value, which is mainly reflected in the value of scientific research, that is, promoting technological progress and benefiting patients and society, it is possible to consider sharing certain information within the scientific community on the premise that the well-being of the individuals who undergo genome editing comes first. This requires that the subject of personal information should be informed of the purpose, the identity of the recipient, etc. separately, and give explicit consent to the sharing of the information, and those using it should refrain from disclosing personally identifiable information. In addition, the birth information of genome-edited infants is also sensitive information. If disclosed, it will cause significant damage to their dignity and other fundamental rights, so strict protection measures should be taken as well. According to Article 1039 of the *Civil Code*, state organs and the chartered institutions assuming administrative functions as well as their staff shall keep confidential the privacy and the personal information of natural persons known to them during the performance of their responsibilities, and shall not disclose or illegally provide it to others. Violators shall be severely punished.

V. The Right to be Free from Discrimination

Before World War II, the right to be free from discrimination only appeared in minority treaties, whose coverage is severely limited. However, with the adoption of the *UN Charter*, "the universal equality of all persons and the absolute prohibition of all forms of discrimination form the core of human rights concepts and systems."[77] Non-discrimination provisions applicable to all persons became a recognized part of international law.[78] Article 14 of the *European Convention on Human Rights* explic-

77. Sun Shiyan, "An Analysis of the Forms of International Human Rights Treaties," *Modern Law Science* 1 (2001): 93, note 6.

78. Li Weiwei, *Equality and Non-Discrimination Under International Human Rights Law* (Oslo: The Norwegian Centre for Human Rights, 2004), 5.

itly lists the prohibition of discrimination as a fundamental human right, according to which "The enjoyment of the rights and freedoms set forth in this Convention shall be secured without discrimination on any ground such as gender, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status." In the case of genetic discrimination, the general language of most international treaties begins with a list of recognized grounds for discrimination. But there are also open-ended expressions, often expressed as "or other status," that allow applications to prohibit discrimination on new, unlisted grounds. The prohibition of discrimination based on genetic features is explicitly included in the list of grounds for discrimination in Article 21 of the *EU Charter of Fundamental Rights*, because genome-related information is highly identifiable and stable. In addition, there are hard and soft legal instruments specifically for bioethics that explicitly respond to current discrimination and stigmatization based on the human genome, such as the *Universal Declaration on the Human Genome and Human Rights* adopted by UNESCO in Paris in 1997. In its Preamble, the Declaration recognizes that "research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole." It also emphasizes that such research should fully respect human dignity, as well as the prohibition of all forms of discrimination based on genetic characteristics. Article 2 (b) provides that "Dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity." Article 6 provides that "No one shall be subjected to discrimination based on genetic characteristics that are intended to infringe or have the effect of infringing human rights, fundamental freedoms and human dignity." "Every effort should be made to ensure that human genetic data and human proteomic data are not used for purposes that discriminate in a way that is intended to infringe or has the effect of infringing human rights, fundamental freedoms or human dignity of an individual or for purposes that lead to the stigmatization of an individual, a family, a group or communities." Similar expressions can also be seen in Article 11 of the European Council's Convention for the *Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine*, Article 7 (a) of UNESCO's *International Declaration on Human Genetic Data* in 2003, and Article 11 of the 2005 *Universal Declaration of Bioethics and Human Rights*.

A. The difference between differential treatment and genetic discrimination experienced by genome-edited people

Considering that it is theoretically possible to identify the information subject by identifying only 30 to 80 specific loci on the gene,[79] and that in practice there is difficulty in anonymizing genetic data, a risk of leakage of identification data in research, and problems with the deduction and identification of data after de-identification, in the case of failure at the front end to protect the right of privacy, which does further harm to human dignity, it deserves more attention how to deal with the potential back-

79. Fida Kamal Dankar, Andrey Ptitsyn and Samar Dankar, "The Development of Large-scale De-identified Biomedical Databases in the Age of Genomics: Principles and Challenges," *Human Genomics* 1 (2018): 2.

end discrimination caused by the disclosure of genetic information. The differential treatment of genome-edited people is different from traditional genetic discrimination. Both, though, can be summed up as unreasonable differential treatment against an individual or his or her family members based solely on differences in their genetic makeup from the "normal" genome. Scholars' arguments against traditional genetic discrimination are weaker in the genome-editing context. First, scholars believe that genes are beyond the control of individuals and that genetic risk is unevenly distributed in society, so a few people should not bear the natural misfortune caused by the genome.[80] However, after an individual is genetically edited, the differences between the genome he/she carries and the "normal" genome are artificially created, and therefore no longer natural. Second, scholars maintain that current genetic information is often obtained based on genetic testing, but in fact, such information is uncertain, has limited predictive value and cannot be used as an absolute indicator.[81] But that point is not persuasive in the genome-editing scenario, because genome editing requires sufficient scientific evidence to link a particular gene to a disease. Third, discrimination based on genetic traits can have a chilling effect. For example, people may avoid taking part in genetic research or using diagnostic tests to avoid avoidable health risks to prevent employers from accessing genetic information that could affect their employment. This is detrimental not only to the health interests of individuals but also to the research interests of the public.[82] However, in the genome editing scenario, the people who have been genetically edited are specific, and the possibility of a large-scale chilling effect is low. Fourth, genetic information goes beyond the individual that carries it. An individual's genetic information may reveal important information about other family members. If a particular variant or disease-causing gene is discriminated against, other family members are also at risk of discrimination.[83] In the case of somatic genome editing, the genome changes only apply to the treated individual. In the case of germline genome editing, it may indeed involve offspring inheriting the modified genome and thus suffering from stigma, too. Still, this clearly does not constitute the core argument against differential treatment. The key reason for this difference is that while traditional discussions of genetic discrimination focus on genetic information based on genetic testing, the differential treatment of genome-edited people is the result of human genetic intervention.

B. The right to be free from discrimination in the context of human genome editing

The essence of discrimination is the infringement of the right to equality, which

80. Anne Mainsbridge, "Employers and Genetic Information: A New Frontier for Discrimination," *Macquarie Law Journal* 1 (2002): 64-66.

81. Carolyn Riley Chapman et al., "Genetic Discrimination: Emerging Ethical Challenges in the Context of Advancing Technology," *Journal of Law and the Biosciences* 1 (2020): 4-6.

82. Margaret Otlowski, Sandra Taylor and Yvonne Bombard, "Genetic Discrimination: International Perspectives," *Annual Review of Genomics and Human Genetics* 1 (2012):440-441. Els Geelen et al., "Unravelling Fears of Genetic Discrimination: an Exploratory Study of Dutch HCM Families in an Era of Genetic Non-discrimination Acts," *European Journal of Human Genetics* 10 (2012): 1019-1021.

83. Tian Ye, "On the Protection of Ethnic Rights in Genetic Research," *Journal of Dalian University of Technology (Social Sciences)* 3 (2019): 56.

is often associated with specific situations in practice. For example, the *Provisions on Causes of Civil Cases* issued by the Supreme People's Court of China clearly defines the cause of "disputes on equal employment rights" under the "disputes on general personality rights." An essential purpose of prohibiting discrimination is to prevent and combat social exclusion. The discussion of whether the differential treatment of genome-edited people constitutes discrimination also needs to be context-specific. So the discussion of whether the differential treatment of genome-edited people constitutes discrimination should go back to what constitutes discrimination, which includes: (1) there is differential treatment, which can be manifested as exclusion or preferential treatment for a certain kind of people or a certain group; (2) the situation of the differentiated population is sufficiently comparable; (3) there is no objective and reasonable reason for differential treatment; (4) the discrimination does not conform to the principle of proportionality.[84] On the contrary, in order to avoid unreasonable differential treatment of individuals, objective and reasonable reasons should be provided to support the differential treatment, and the specific practice should conform to the requirements of the proportionality principle.

In the current public discussion, children born after genome editing are regarded as "monsters" and "variants," and many voices call for sterilization or quarantine of them. Whether such opinions conform to human rights norms needs to be considered. Specifically, one of the questions is: can authorities force genome-edited infants to undergo more frequent physical examinations or health tests than ordinary children? On the one hand, these requirements of regulatory authorities do have a legitimate purpose because of the public interest in public health and biosecurity, the need to obtain necessary research data, and the need to protect the health of genome-edited infants. On the other hand, special protection for minors must be taken into account. The frequent physical examination will cause unnecessary damage not only to their physical but also to their psychological development. It will make them realize that they are "problem children" different from ordinary people, which will have a very negative impact on their personality development. Routine clinical and developmental examinations can be performed for genome-edited infants based on the fundamental legal principle of proportionality. Still, the necessity of whole genome sequencing is relatively weak, and thus, repeated, frequent physical examinations constitute an unjustified discriminatory measure. Exceptions such as whole genome sequencing can only be limited to the specific circumstances of the exception (for example, when there are reasonable grounds to believe that the person may have a congenital disease or defect).

The second question is: should genome-edited infants be restricted in their freedom to marry and have children when they reach adulthood? While genome-edited infants constitute a special group, it does not interfere with their fundamental rights as human individuals. Therefore, the establishment of the first two constitutive requirements should be clear, the core of which is to investigate whether there are objective

84. Lu Haina, *State Protection of Equal Employment Rights in China: From the Perspective of International Law* (Beijing: Law Press · China, 2015), 9-13.

and reasonable major reasons for restricting or even depriving basic rights and whether the means and degree of restriction are in proportion to the goal to be achieved. China's *Civil Code* only prohibits the marriage of direct blood relatives and collateral blood relatives up to three generations, and no longer prohibits the marriage of natural persons suffering from specific diseases. Therefore, there is no legal basis for restricting the freedom of marriage of people who have been genetically edited. Theoretically, it may arouse public concern that off-target genes in people with germline genome editing can be passed on to future generations, contaminating the human gene pool. It may be justified on the grounds of public interest (where there is objective evidence of such a risk) to restrict the freedom of reproduction, but that does not apply to the freedom of marriage. Individual rights do sometimes need to take a back seat to the common good, given the overall fate of the community to which it is linked. However, it should be clear that the restriction of public interest is an exception to protecting individual rights. When it is necessary to restrict individual rights for public interest consideration, the proper protection of individual interests must be realized through procedural justice. Therefore, the restriction of reproductive freedom also needs to conform to the principle of proportion. It is necessary to thoroughly investigate the negative impact and degree of natural reproduction of people with germline genome editing and to have various alternative options for their offspring. In other words, natural selection can be allowed if there are no adverse effects of natural reproduction. If there is a negative effect, considering the desire of the individual to have direct blood relatives, it may be considered whether they can be allowed to perform preimplantation genetic diagnosis, so as to minimize any adverse effects caused by the restriction of their reproductive freedom.

From the above restrictions on the two specific rights, it is not difficult to see that, on the one hand, genome-edited infants deserve human rights and dignity, just like normal people. But on the other hand, given that their genome has been edited, they inevitably form a new group of human beings with specificities and vulnerabilities that require them to be treated differently from naturally conceived children, with special protection that ensures full respect for their dignity. However, this special protection needs to meet more strict conditions, including the objective and reasonable necessity and requirements in line with the principle of proportionality. This attitude of special protection is different from the laissez-faire attitude that can lead to chaos and disorder. It is also different from putting genome-edited infants under strict monitoring and depriving them of their freedom of movement. Instead, it carries out necessary regulation in a manner that respects the best interests of the genome-edited infants.

In addition, from another aspect of the right to be free from discrimination, the development of genome editing technologies risks deepening social injustices. Because even genome editing for therapeutic purposes is difficult to achieve equal utilization due to its high price, which can widen the health and medical disparities that already exist. Besides, the use of genome editing for disease treatment may have the side effect of increasing stigma or discrimination against people with disabilities

or specific groups of patients. In this regard, the state should first carefully assess the potential ethical and social justice issues concerning the use of technologies. Second, access to the equitable use of genome editing technologies should be improved once it is safe and effective. Finally, flexible methods such as popular science and education should be used to promote social inclusion and increase awareness and understanding of special disease groups and genome editing technologies.

VI. Conclusion

Needless to say, genome editing holds unparalleled promise for correcting inherited mutations, treating inherited rare diseases, and understanding early human development. As the technologies mature and safety improves, it is likely that it will be gradually approved for clinical trials and applications in the future. In this regard, this paper particularly highlights the obligations of three key actors. First, at the forefront of technological innovation, researchers should fully assess the short-, medium-, and long-term impacts of the development of genome editing technologies on society and human populations, especially the potential risks and side effects. Second, as the safety valve of technological innovation, the ethics committee should shoulder the due responsibility of review, comprehensively review the technical risks, ethical conflicts and social impacts, and make responsible decisions that meet the professional level and public expectations. Third, public participation and dialogue are necessary for the application of new technologies. Relevant institutions should organize experts from various fields such as medicine, ethics, and law to provide necessary science education to the public to help the public understand and embrace the diversity of life forms instead of labeling those who are different as excluded or rejected, so as to avoid stigmatization and discrimination.

Finally, it should be emphasized that although the human rights perspective of this paper does not restrict the subject of obligations to the state, state obligations are still the most important link in the protection of human rights because the state undoubtedly has the most resources and means to provide thorough protection of individual human rights. It should be acknowledged that after the exposure of the genome-edited infant incident, the relevant national departments made timely and reasonable disposal and response. In particular, they made a series of targeted direct responses to genome editing technologies and human life science research in legislation, thus providing a legal basis for the protection of human rights. In the long run, to effectively implement the requirements of the *Constitution*, such as "the state respects and protects human rights," and effectively promote the modernization of the country's governance system and capacity, relevant departments should, on the basis of thoroughly studying relevant experiences at home and abroad and widely soliciting opinions from relevant parties, timely enact or amend relevant laws (such as legislation on human assisted reproductive technologies) to comprehensively protect the fundamental human rights of subjects and genome-edited people in genome editing scenarios.

(Translated by *CHEN Feng*)