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Personal Rights of the Embryo in the Context of Genetic Editing Technology: A Guideline for Improving the Law Based on Japanese Legal Experience

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Abstract— *The evolution of genome editing technology poses significant challenges in identifying and safeguarding the personality rights of human embryos. While such technology directly impacts fundamental personality rights, including the right to life, the right to bodily integrity, and genetic identity - the current absence of an explicit legal status under Vietnamese civil law renders the protection mechanisms for embryonic personality rights ambiguous and lacking a formal legal basis. This article focuses on analyzing the protective frameworks for embryonic personality rights within the context of gene editing, elucidating the approach adopted by Japanese law in reconciling the freedom of scientific research with the preservation of human dignity. Based on an analysis of Japanese legislative perspectives, the article proposes orientations for the refinement of Vietnamese legislation concerning the protection of embryos as gene editing technology becomes increasingly prevalent.*

Keywords— *Bioethics, genome editing technology, human embryo, personality rights.*

I. Introduction

The rapid development of gene editing technologies has generated significant prospects for the prevention and treatment of genetic diseases. At the same time, these technologies raise serious legal and ethical challenges, as they enable direct human intervention in the genetic structure from the embryonic stage. Global debates on the limits of embryo research and the protection of human rights in the life sciences demonstrate the complexity of this issue and the need for timely legal regulation. However, Vietnamese civil law does not currently recognize the embryo as a subject of rights, resulting in a regulatory gap in the protection of personality rights such as the right to life, bodily integrity, and genetic identity. Against this background, examining mechanisms for the protection of embryonic personality rights under the impact of gene editing technologies is necessary. Drawing on French legislative experience, this study proposes directions for improving Vietnamese law in this field.

II. Overview of Mechanisms for the Protection of Embryonic Personality Rights under the Impact of Gene Editing Technologies

A. Overview of Gene Editing Technologies

According to scientific perspectives, Gene Editing is a biotechnological technique that enables precise and effective modification of genetic components within the DNA of living organisms [1]. When interventions are carried out on the germline or at the embryonic stage, such modifications may be heritable across generations, thereby creating potential for the prevention of genetic diseases [2]. According to Jennifer Doudna, one of the inventors of the CRISPR Cas9 technology, gene editing is defined as "the use of biological tools to intervene in an organism's DNA in order to modify or repair defective gene sequences," drawing on the natural defense mechanisms of bacteria and unicellular microorganisms [3]. Beyond medicine, this technology is also widely applied in agriculture and biological sciences.

At present, five principal groups of gene editing technologies can be identified. Among them, CRISPR Cas9 is particularly prominent due to its high efficiency, low cost, and operational simplicity. TALEN and ZFN allow more precise DNA cleavage but involve more complex design processes. Newer technologies such as Base Editing and Prime Editing aim to enhance precision and reduce off target effects, reflecting a trend toward safer and more sustainable development in this field.

B. Concept and Characteristics of the Embryo

First, with regard to the concept of the embryo. According to the World Health Organization (WHO), the embryo is defined as the early stage of human development, beginning from the moment of fertilization and lasting until the end of the eighth week of gestation [4].

In terms of biological characteristics, the embryo carries the complete genetic makeup of a human individual and possesses the potential to develop into a fully formed human being if nurtured under appropriate conditions. Following fertilization, the embryo undergoes successive stages, including cell division (cleavage) forming the zygote; the blastocyst stage, during which cells differentiate into two layers, namely the inner cell mass, which forms the body, and the outer layer, which develops into the placenta; and gastrulation, during which three primary germ layers (ectoderm, mesoderm, and endoderm) are formed, providing the foundation for the development of human organs [5]. At this stage, however, the embryo lacks a fully developed nervous system, consciousness, and the capacity to perceive

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pain [6]. Accordingly, although the embryo is a living entity with a complete genetic code, it does not yet exhibit the characteristics of a conscious individual with subjective experience.

It is also necessary to distinguish between the embryo and the fetus, a distinction of importance in both medicine and law, reflecting the difference between biological life and legal life. The fetus represents the subsequent stage of development after the embryonic period, during which organs have taken shape and begun to function. While the embryo is generally regarded as an object of research or assisted reproduction, the fetus from the ninth week onward is more closely associated with the right to life and prenatal legal protection [7]. From the perspective of developmental biology, the embryo thus constitutes an entity of potential life, but lacks the level of awareness required to be considered an independent human individual. This understanding forms the basis for legal debates concerning the legal status of the embryo in the context of the rapid advancement of gene editing technologies [8].

C. *Overview of Personality Rights and Mechanisms for Their Protection*

Personality rights constitute a set of fundamental rights inherently attached to each individual, reflecting human dignity and bodily integrity. In principle, personality rights are non proprietary in nature, characterized by inalienability and non waivability, and are subject to absolute legal protection [9]. They provide the normative foundation for recognizing and safeguarding the value of the human being as an autonomous subject in society. From a bioethical perspective, the scope of personality rights extends into the domain of genetic rights, encompassing the right to genetic integrity, the right to autonomous decision making in medical interventions, and the right to be born free from avoidable genetic harm [10].

In the context of gene editing technologies, mechanisms for protecting the personality rights of embryos must maintain a balance between technological advancement and respect for human dignity. Accordingly, such mechanisms include protection grounded in ethical and dignity based values, viewing the embryo as an entity possessing potential life and linked to the principle of respect for human life; protection through legal norms that impose limits on interventions in the human body and genetic material and establish legal liability for infringements; and protection through oversight and control by bioethical and judicial bodies [8]. Thus, the protection of embryonic personality rights is not a purely legal matter, but rather an integrated endeavor combining law, ethics, and science.

D. *Impact of Gene Editing Technologies on the Personality Rights of the Embryo*

First, from a medical perspective, gene editing technologies have ushered in a new era in reproductive medicine and the treatment of genetic diseases. In reproductive medicine, the use of techniques such as preimplantation genetic diagnosis or testing (PGD PGT) combined with gene editing enables direct intervention in the genome to eliminate pathogenic mutations or enhance immune resistance [1]. These advances offer substantial promise for preventing hereditary diseases, but they also alter the embryo's natural biological character, transforming it from a naturally developing entity into one that can be technologically designed [11]. Such interventions further allow the selection of genetic traits, including disease resistance, physical characteristics, and cognitive potential [3]. In this context, gene editing directly affects conceptions of embryonic dignity and humanity by introducing a new boundary between being naturally born and being a technological product. In practice, the capacity for genetic modification has pushed the embryo beyond the traditional scope of civil law, which recognizes legal capacity only from birth. This development necessitates a redefinition of the objects of legal protection to include embryos subjected to biotechnological intervention.

Second, from a social ethical perspective, gene editing raises a fundamental moral question concerning the boundary between therapy and the design of human beings. It calls into question whether humans may choose life itself, given that every intervention in an embryo may affect future generations. The United Nations Educational, Scientific and Cultural Organization (UNESCO), in the 2005 Universal Declaration on Bioethics and Human Rights, emphasized the principle that "human dignity must be respected at all stages of life, and human beings must not be treated merely as means for scientific research." Accordingly, gene editing must be situated within a framework of respect for dignity and humanity, avoiding the commercialization or objectification of human embryos. The World Health Organization (WHO), in its 2021 Recommendations on Human Genome Editing, called for a moratorium on the use of gene editing for reproductive purposes, permitting research only within laboratory settings and under strict supervision by national ethics committees. This recommendation reflects the international community's reliance on ethics as a soft constraint. In reality, however, the pace of technological development is outstripping the regulatory capacity of traditional ethical norms. To ensure humanitarian principles in research and application of gene editing technologies, states must therefore establish binding legal rules capable of limiting and sanctioning abusive practices involving human embryos.

Third, from a legal perspective, gene editing technologies have destabilized traditional civil law concepts concerning subjects of rights, thereby exposing serious gaps in mechanisms for protecting personality rights. This development creates a need for the law to expand the scope of protected entities to include embryos. In this sense, gene editing has become a driving force prompting legal evolution from a system focused solely on protecting individuals after birth toward one that also safeguards life in formation. Thus, gene editing technologies both extend the reach of science into the domain of human life and compel the law to redefine the notion of the subject of rights. In this context, technology functions not only as a source of legal challenges, but also as a catalyst for the development of legal systems toward more

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comprehensive protection of human dignity and personality rights from the earliest stages of life.

III. Japanese Legal Experience on Mechanisms for Protecting Embryonic Personality Rights in the Context of Gene Editing Technologies

A. Japan's Current Legal Framework on Research and Genetic Intervention in Embryos

Japan is regarded as one of the states that developed an early and highly flexible governance framework for biotechnology. Unlike the European model, particularly in France and Germany where binding legislation is used as the primary regulatory instrument, Japan relies on a system of administrative guidance (soft law) combined with ethical review mechanisms and social responsibility.

First, Article 13 of the 1947 Constitution of Japan provides that "all citizens shall be respected as individuals; their right to life, liberty, and the pursuit of happiness shall, to the extent that it does not interfere with the public welfare, be the supreme consideration in legislation and in other governmental affairs." This provision constitutes a constitutional basis for protecting human dignity and personality rights, which encompasses respect for genetic interests and reproductive health.

Second, the Japanese Civil Code (Minpō) sets out general principles on personality rights (人格権, jinkaku ken), privacy, and rights relating to the human body. Although it contains no rule directly addressing the embryo, a number of Japanese scholars argue that these principles "extend to the formative stage of human life" [12]. In certain cases concerning assisted reproduction, Japanese courts have also invoked personality rights as an ethical legal foundation for delimiting the boundary between scientific interests and human dignity [13].

Third, Japan relies on sector specific guidelines issued and supervised by the Ministry of Education, Culture, Sports, Science and Technology (MEXT) and the Ministry of Health, Labour and Welfare (MHLW). Notably, the 2019 Guidelines for Genome Editing Research on Human Embryos stipulate that genome editing on human embryos is permitted only for basic scientific research purposes and not for reproductive purposes, and that all research must be approved by an ethics committee [14]. The 2020 Guidelines on Assisted Reproductive Medicine issued by MHLW prohibit implantation of edited embryos into a human uterus and require destruction of embryos after 14 days from fertilization [15]. The 2010 Guidelines for Handling of Specified Embryos, as amended in 2021, regulate the use of embryos in regenerative medicine and stem cell research.

Fourth, the Japanese Penal Code (Keihō) does not contain a specific provision on gene editing. However, unlawful creation, use, or destruction of human embryos may be addressed under provisions relating to infringement of human dignity and violations of rules governing reproductive medicine [16].

Overall, Japan's framework combines hard law (constitutional, civil, and criminal law) with soft guidance instruments (guidelines). This design preserves legal authority while remaining adaptable to developments in genetic technologies, a feature that many scholars describe as a model of soft bioethics governance [17].

B. The Japanese Legal Approach to the Personality Rights of the Embryo under the Impact of Gene Editing Technologies

Japanese law does not recognize the embryo as an independent legal subject, but acknowledges it as potential human life, an entity deserving ethical and legal respect. This position is clearly reflected in biomedical research guidelines, which characterize the embryo as an "object of respect" rather than a "bearer of rights" [14]. Under the doctrine of seimei sonchō (respect for life), personality rights do not commence at birth but operate as a universal ethical principle governing the formative stages of human life. Japanese legal scholars such as Ōnuma Yasuaki and Sugeno Kazuo argue that, although the embryo lacks legal capacity, it remains a moral entity requiring protection against genetic interference [18].

This approach reflects a reconciliation between scientific freedom and bioethical constraints. Japan does not adopt an absolute prohibition model as in Germany, yet it does not permit unrestricted research. The authorization of gene editing on embryos solely within the context of non reproductive research demonstrates a deliberate distinction between therapeutic purposes and the creation or design of human beings, a core boundary in the protection of personality rights [15].

C. Mechanisms for the Protection and Oversight of Gene Research on Embryos in Japan

Japan maintains a two tier oversight model combining self regulation within the scientific community and administrative supervision by the state. First, internal oversight is exercised through Institutional Review Boards (IRBs). Each research institution establishes an independent ethics committee responsible for assessing ethical risks, biosafety concerns, and the legality of proposed research. Only after IRB approval may a research project be submitted to the competent ministries for formal authorization [14]. Second, administrative oversight is carried out at the national level. Central authorities, including the Ministry of Education, Culture, Sports, Science and Technology (MEXT) and the Ministry of Health, Labour and Welfare (MHLW), are empowered to approve, suspend, or revoke research activities. In addition, the Council for Science, Technology and Innovation (CSTI), operating under the Cabinet, provides strategic advice and issues policy recommendations shaping national bioethics governance [19].

Japan consistently upholds three core principles in the oversight of gene research. These are the prohibition of gene editing on human embryos for reproductive purposes, the prohibition of heritable genetic modifications transmitted to future generations, and the absolute ban on commercialization

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or trade in human embryos in any form [19]. This framework reflects an ethics oriented approach to law, in which law functions as an outer layer of protection while bioethics operates as the inner mechanism of control. Such a design enables Japan to preserve scientific research freedom while ensuring effective protection of the personality rights and human dignity of the embryo.

IV. Vietnamese Law on Mechanisms for the Protection of Embryonic Personality Rights under the Impact of Gene Editing Technologies and Proposed Directions for Legal Reform

A. Legal Gaps in the Protection of Embryonic Personality Rights in the Context of Gene Editing Technologies

At present, Vietnamese civil law lacks a clear legal definition of the "embryo," which creates difficulties in establishing and protecting the personality rights of this entity. Within the Vietnamese civil law system, Article 16 of the 2015 Civil Code provides that "the civil legal capacity of an individual commences at birth and terminates upon death," according to which only persons who have been born and are alive may be subjects of legal rights and obligations. Clause 5 Article 2 of Decree No 10/2015/ND CP defines the embryo as "the product of the fusion between an ovum and a sperm." Certain provisions, such as Article 613 of the 2015 Civil Code concerning inheritance rights of the unborn child and Article 94 of the 2014 Law on Marriage and Family concerning determination of parentage in cases of assisted reproduction, regulate only the fetus. At the same time, Vietnamese law contains no provision directly addressing the legal status of the embryo, with the result that the embryo, as the earliest stage of human life, is treated merely as an object of medical practice, scientific research, or assisted reproduction, rather than as a subject of rights. This creates significant difficulties in assessing the legality of activities such as gene editing, embryo storage, and embryo destruction in reproductive medicine and scientific research.

Vietnamese law has not established a mechanism for protecting the personality rights or biological dignity of the embryo, resulting in a regulatory vacuum with respect to direct interventions in embryonic genetic material. Under Article 25 of the 2015 Civil Code, personality rights are inherent to each individual and include the right to life, bodily inviolability, honor and dignity, and protection of privacy. However, because the embryo has not been recognized as having legal status equivalent to that of an individual, these personality rights do not apply to the embryo. As a consequence, any intervention or experimentation involving embryos lacks a clear legal basis for determining whether it constitutes a violation.

In practice, when acts such as gene editing, experimentation, or destruction of embryos occur, there is no provision clearly classifying such conduct as an infringement of personality rights, a breach of ethical norms, or merely a lawful scientific activity. This situation not only leaves embryos insufficiently protected, but also increases the risk of commercialization of human embryos.

In addition to conceptual and legal status gaps, Vietnam also lacks an effective bioethics control mechanism governing research and application of gene editing technologies on embryos. This deficiency limits Vietnam's capacity to manage human embryo research, particularly as medical institutions have already applied preimplantation genetic testing techniques (PGT PGD) that approach the boundaries of gene editing technologies. Currently, the evaluation and approval of research projects involving human embryos are primarily carried out by the National Council for Ethics in Biomedical Research, established under Circular No 43/2024/TT BYT dated 12 December 2024. However, this mechanism remains largely administrative and advisory in nature, lacking binding legal force or effective sanctions for violations. Moreover, legal liability in cases where embryos are destroyed, improperly modified, or unlawfully used has not been clearly regulated in the Civil Code or relevant specialized legislation.

B. Recommendations for Vietnamese Law on Mechanisms for the Protection of Embryonic Personality Rights under the Impact of Gene Editing Technologies

Japanese experience demonstrates that the protection of embryonic personality rights does not necessarily require recognition of the embryo as an independent legal subject, but may instead be achieved through indirect protective mechanisms grounded in respect for human dignity and biosafety. On this basis, the authors propose the following directions for improving Vietnamese law.

First, it is necessary to establish a clear concept and special legal status of the human embryo within the Civil Code. A definition should be introduced as follows: "An embryo is a cell formed from the fusion of an ovum and a sperm, carrying the complete genetic makeup of a human individual and possessing the capacity to develop into a human being under appropriate conditions." Accordingly, the embryo should be recognized as a biological entity with ethical value, protected by law within the framework of potential personality rights.

Second, the scope of personality rights should be expanded to encompass the field of genetics. Vietnam should recognize and protect a number of new personality rights appropriate to the context of gene technologies, including the right to genetic integrity, the right to be free from unauthorized interference with genetic material, and the right to protection of biological identity and personal genetic data. These rights are consistent with the principles set out in the UNESCO Universal Declaration on Bioethics and Human Rights of 2005, which emphasizes respect for human dignity and biological autonomy [20].

Third, an independent bioethics oversight mechanism should be established. Following the Japanese model, Vietnam should create a National Bioethics Council operating independently, with functions including licensing and supervising research involving human gene intervention, assessing ethical and social risks of gene editing technologies, and issuing periodic policy recommendations and warnings to

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the Government. This model would facilitate coordination among the state, the scientific community, and civil society in the governance of biological research.

Fourth, Vietnam should combine hard law with soft law in the governance of gene technologies. Drawing on Japanese experience, Vietnam may adopt administrative guidelines issued by the Ministry of Health and the Ministry of Science and Technology, specifying procedures, technical limits, and ethical principles applicable to research on human embryos. These guidelines constitute a flexible regulatory tool that can be updated more rapidly than statutes, while remaining binding through licensing and research accreditation mechanisms.

Fifth, Vietnam should move toward the adoption of a National Bioethics Law. In the long term, a comprehensive statute is needed to regulate biomedical issues, gene technologies, genetic data, and the protection of human personality rights in an integrated manner. Such a law should reflect the spirit of the Japanese model, with ethics as the foundation and law as the guarantee, in order to maintain a balance between scientific development and the protection of human beings.

The improvement of the legal framework should be guided by four principles: respect for human dignity and the right to life of all biological entities with potential life; assurance of biosafety and medical ethics in all research activities; balance between scientific freedom and social responsibility; and multi stakeholder coordination among the state, the scientific community, and the public in the oversight of gene editing technologies.

These directions would not only help to address existing legal gaps, but also enable Vietnam to proactively engage with international trends and to build a humane, modern, and technology adaptive legal framework capable of safeguarding personality rights in the biological era.

V. Conclusion

The development of gene editing technologies poses unprecedented challenges to legal systems, particularly with respect to protecting the personality rights of entities situated at the boundary between biological life and legal life. Japanese experience demonstrates that protection of the embryo need not be tied to recognition of independent legal personality, but may instead be achieved through flexible ethical legal mechanisms grounded in respect for human dignity and biosafety. For Viet Nam, legal reform should aim to establish a special legal status for the human embryo, expand the scope of personality rights into the field of genetics, and develop an independent bioethics oversight mechanism. A legal framework that harmonizes science, ethics, and human rights will provide the foundation for ensuring that technological progress does not exceed the humane limits of law.

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