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ARTICLE

THE INTERSECTION OF HUMAN RIGHTS AND BIOETHICS IN INTERNATIONAL LAW (A COMPARATIVE STUDY OF GENETIC TECHNOLOGY REGULATION IN THE ASEAN REGION

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Abstract

This study explores the relationship between Human Rights (HAM), bioethical principles, and the international legal framework in responding to the rapid development of genetic technology. The background of this study is based on the legal vacuum and ethical dilemmas related to genetic editing, cloning, and DNA manipulation that have the potential to violate human dignity and the right to genetic integrity. The main problem arises when scientific innovation exceeds the speed of legal regulation, thus triggering the risk of genetic discrimination and the commodification of life. The formulation of the problem in this study is: (1) How are bioethical principles integrated into international human rights instruments to regulate genetic technology? and (2) How do the legal policies of ASEAN countries compare in protecting their citizens from the misuse of genetic technology? The research method used is normative juridical using a conceptual approach to examine bioethical theory, a legislative approach to international instruments such as the Universal Declaration on Bioethics and Human Rights, and a comparative approach in the ASEAN region (particularly a comparison between Indonesia, Singapore, and Thailand). The results of the study indicate that although international instruments have laid the foundation for protecting human dignity, implementation at the ASEAN regional level is still very fragmented. Singapore has highly permissive regulations for biomedical advancement, while other countries still rely on general ethical norms without a strong legal framework. In conclusion, harmonization of scientific progress and the protection of fundamental rights is necessary to prevent genetic technology from harming humanity. Suggestions include the establishment of legally binding ASEAN regional bioethics guidelines and the strengthening of domestic legislation that specifically prohibits genetic discrimination.

Keywords: Bioethics, Genetic Technology, Human Rights, International Law.

A. INTRODUCTION

The contemporary biotechnology revolution has reached an unprecedented culmination through the discovery of the CRISPR-Cas9 gene-editing technology. Jennifer Doudna describes this moment not merely as the arrival of another laboratory tool, but as an extraordinary force “a crack in creation” that grants humans the capacity to steer their own biological evolution (Jennifer et al., 2017). On the one hand, this technology carries transformative medical promise, particularly for curing lethal genetic diseases; on the other hand, it opens an ethical “Pandora’s box” concerning embryo manipulation (germline editing) that could permanently alter the very nature of humanity (Aliyev & Eyvazova, 2025). The deepest anxiety embedded in this trajectory is the emergence of a “post-human” era, as

warned by Francis Fukuyama, in which uncontrolled genetic engineering risks eroding the essence of human equality that underpins liberal democracy (Fukuyama, 2022).

Confronting a pace of technological change that outstrips legal development, the international community through UNESCO has articulated normative standards in the *Universal Declaration on Bioethics and Human Rights* as an effort to ensure that human dignity remains the primary benchmark for scientific innovation (Henk et al., 2009). The Declaration affirms the principles of autonomy and informed consent; however, the distinctive character of genetic data, with its inherently familial implications, calls for a paradigmatic shift from an ethics centered on the individual toward principles of solidarity and collective responsibility (Bartha & Ruth, 2005). Moreover, there is an evident tension between the right to benefit from scientific progress and the right to bodily integrity: without robust oversight, this technology may become a new vehicle for discrimination or merely a commodified instrument that deepens social inequality under the influence of large corporate actors (Aliyev & Eyvazova, 2025).

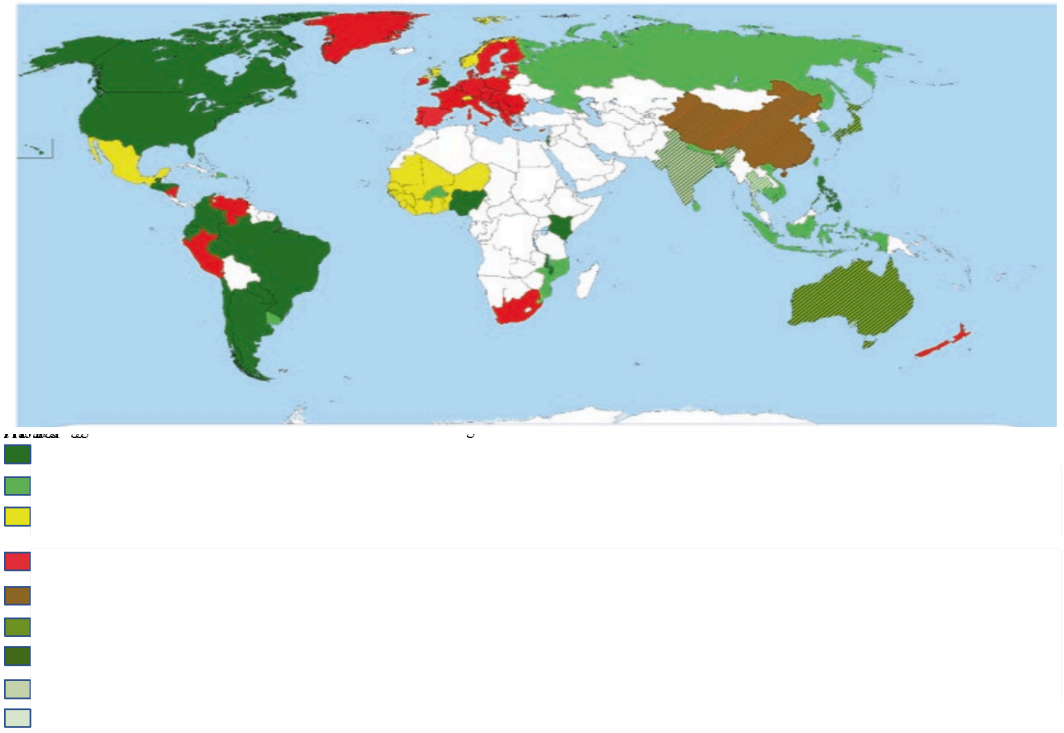

Figure 1. Map of Genome Editing in Biotechnology Regulation Around the World
Source: Sprink, T., Wilhelm, R., Hartung, F.: Genome editing around the globe: an update on policies and perceptions. Plant Physiol. 190, 1579–1587 (2022). https://doi.org/10.1093/plphys/kiac359

In Asia, particularly ASEAN, the ambition to become a global biomedical hub often outpaces the readiness of regulations that protect fundamental human rights. Research shows that Ethical, Legal, and Social Implications (ELSI) practices in this region often emphasize technological advancements over strict legal restrictions, creating a heterogeneous and dynamic regulatory landscape (Go et al., 2014). Based on these ethical complexities and existential risks, an in-depth analysis of how international legal norms respond to biotechnological advances is needed to ensure that human dignity is not marginalized by scientific ambitions. To address this challenge, the next section of this paper will explore the intersection of human rights and bioethics in international law, focusing on a comparative

study of genetic technology regulations in the ASEAN region. This analysis aims to map the extent to which legal frameworks in Southeast Asia have been able to protect the bodily integrity and fundamental rights of their citizens amidst the dynamics of global innovation.

B. LITERATURE REVIEW

Human Dignity

Human dignity holds that every individual possesses intrinsic value that does not depend on status, capacity, or social utility, thereby serving as a normative foundation for human rights and global bioethics (Andorno, 2009; Beyleveld & Brownsword, 2001). Within this framework, biotechnological innovation—including genomic interventions is considered legitimate only insofar as it does not reduce human beings to objects, commodities, or merely instruments for achieving scientific goals (Beyleveld & Brownsword, 2001). UNESCO positions human dignity as a primary benchmark to ensure that scientific progress remains within the corridor of human protection and does not produce dehumanization (UNESCO, 2005; ten Have & Jean, 2009). In legal terms, the Council of Europe through the Oviedo Convention affirms the "primacy of the human being," meaning that human interests and well-being must prevail over the interests of science or society (Council of Europe, 1997). Accordingly, dignity functions as a protective boundary that can justify restricting or prohibiting certain biomedical practices when those practices risk eroding human integrity (Faunce, 2005; Andorno, 2009). Indicators:

- Recognition of intrinsic human worth (*intrinsic worth*)
- The principle of the "primacy of the human being"
- Prohibition of commodification of the body/genetic information
- Restrictions on interventions that alter human essence
- Protection of human integrity and genetic integrity

Autonomy and Informed Consent

Autonomy positions the individual as the primary decision-maker over their body and biological data, so informed consent is understood as recognition of self-determination rather than a mere documentary formality (Council of Europe, 1997; UNESCO, 2005). In this approach, valid consent requires adequate information, reasonable understanding, and freedom from coercion especially in medical interventions and research settings (UNESCO, 2005; ten Have & Jean, 2009). In genetic contexts, the quality threshold for consent is higher because genetic information is predictive, has long-term effects, and often carries implications for families and communities (Anderson, 2004). The Oviedo Convention affirms that interventions may only be carried out after free and informed consent is obtained, while also requiring special protection for vulnerable persons (Council of Europe, 1997). At the intersection of human rights and bioethics, informed consent becomes a key safeguard that prevents experimentation or biological data extraction practices that may compromise human integrity and dignity (Faunce, 2005). Indicators:

- Sufficiency of information (risks, benefits, alternatives)
- Subject comprehension (*comprehension*)
- Voluntariness / absence of coercion (*voluntariness*)
- Capacity/competence to provide consent
- Consent documentation and process traceability
- Right to withdraw consent (*withdrawal*) and ongoing control

Genetic Justice: Non-Discrimination and Privacy

Genetic justice emphasizes the fair distribution of benefits from genomic science while minimizing inequality and preventing genetic discrimination in social domains (e.g., employment and insurance) (Knoppers & Chadwick, 2005; UNESCO, 1997). UNESCO's

Declaration on the Human Genome provides a normative reference for rejecting differential treatment based on genetic characteristics, as such practices can undermine human dignity (UNESCO, 1997). Privacy is central because genetic data are highly identifying and can produce social harms when accessed, processed, or shared without the data subject's control (Anderson, 2004). In modern biobank governance, justice also concerns "who gets what" from research outputs for example, policies on returning individual results or incidental findings, so that benefits do not remain confined to research institutions alone (Zawati & Knoppers, 2012). For these reasons, the combination of genetic non-discrimination and genetic privacy strengthens the legitimacy of more binding regulation, particularly where policy and legal practice remain fragmented across countries (Awori, 2010; Faunce, 2005). Indicators:

- Principle of genetic non-discrimination
- Confidentiality and restricted access to genetic data
- Data governance: processing purpose, minimization, and subject control
- Return-of-results / incidental findings policies
- Equality of access to benefits (*benefit sharing*) and inequality prevention
- Accountability and remedy mechanisms when violations occur

C. RESEARCH METHODOLOGY

According to Soerjono and Sri (2001), this research is a normative legal research (doctrinal research), which focuses its study on the inventory, synchronization, and harmonization of various legal norms and bioethical principles related to the development of the latest genetic technology such as CRISPR. To answer the established problem formulation, this research uses several approaches as follows. First, the statute approach, carried out by examining various international legal instruments that form the foundation of global bioethics, including the Universal Declaration on Bioethics and Human Rights (2005) and the Universal Declaration on the Human Genome and Human Rights (1997) (Henk et al., 2009). This approach also includes an analysis of relevant genetic regulations, such as the Personal Data Protection Law in Indonesia, to evaluate the extent to which these instruments are able to protect the privacy rights of citizens. Second, the conceptual approach. This approach is used to examine fundamental doctrines in bioethics and human rights, such as human dignity, individual autonomy, and genetic justice theory, in addressing the risks of modern eugenics. This study draws on critical thinking regarding the impact of the biotechnology revolution on liberal democratic order and the very nature of humanity. A comparative approach is employed, comparing the dynamics of national regulations in the ASEAN region, which tend to prioritize technological advancement, with those in other jurisdictions that have stricter legal classifications regarding genetically modified organisms and germline manipulation (Sprink & Wilhelm, 2023). This comparison is crucial for mapping the heterogeneity of global regulations, which poses a challenge to international ethical standardization.

The data used are secondary data consisting of primary legal materials (international treaties and declarations), secondary legal materials (textbooks, scientific journals such as Nature Reviews Genetics and Genome Medicine, and reports from international organizations), and tertiary legal materials. Data collection was conducted through library research. All collected materials were then analyzed qualitatively using descriptive-analytical methods to produce prescriptive conclusions regarding the reconstruction of state responsibility in protecting human rights in genetic engineering (Marzuki, 2017).

D. RESULT AND DISCUSSION

Bioethics as the Soul of Human Rights in International Law

Bioethics has now transformed from a purely moral discourse into an integral component of international legal norms, operating through both hard law (such as treaties) and soft law (such as declarations). The principal framework that integrates these two normative layers rests on three fundamental pillars:

Human Dignity: The Ontological Foundation and Imperative Norm of Bioethics

The concept of human dignity in global bioethics is not merely a rhetorical ornament; it functions as an ontological foundation that legitimizes the entire architecture of international biomedical law (Andorno, 2023). Within international legal discourse, human dignity is understood as an intrinsic value inherent in every individual without exception an idea rooted in Kantian thought that human beings must always be treated as ends in themselves, never merely as means to other ends (Beyleveld & Brownsword, 2001). In the era of modern biotechnology, this principle faces a major challenge in the form of the "commodification of the body," in which parts of the human body, including genetic information, are increasingly treated as economic assets. UNESCO, through the *Universal Declaration on Bioethics and Human Rights* (2005), explicitly positions human dignity as the first pillar to prevent such dehumanization (UNESCO, 2025).

The urgency of human dignity becomes even clearer when we consider the risks posed by genetic interventions that may alter the very essence of humanity. Roberto Andorno emphasizes that dignity operates as a "protective boundary" against genetic engineering efforts that could undermine the integrity of the human species. Without a strong genetic moral framework, technologies such as germline gene editing could lead to a new era of eugenics, in which a person's worth is judged by biological "quality." For this reason, international law maintains that human dignity is absolute and cannot be diminished even in the name of scientific progress or collective societal interests (Faunce, 2005).

Furthermore, the application of human dignity in bioethics also includes the protection of vulnerability. This principle requires that individuals with physical or mental limitations receive enhanced safeguards to prevent exploitation in medical research (Ten, 2009). In the view of Deryck Beyleveld and Roger Brownsword, dignity must be embedded within public policy so that every medical innovation continues to respect human autonomy and well-being (Maclean, 2002). In this sense, dignity is not only a philosophical concept, but an operational legal norm that obliges states and medical institutions to prioritize humanity over technological ambition.

Informed Consent: A Manifestation of Autonomy and the Sovereignty of the Biomedical Subject

Informed consent (*Persetujuan Setelah Penjelasan*) is a core legal instrument protecting individual autonomy in every medical intervention and scientific research activity (Anderson, 2004). Juridically, this principle is grounded in rights to personal liberty and bodily integrity recognized by various human rights instruments. Consent is valid only when it is given voluntarily, free from coercion, and preceded by comprehensive information regarding procedures, risks, benefits, and alternatives (UNESCO, 2005). These requirements are explicitly reinforced in the Oviedo Convention (1997), which affirms that the interests and welfare of the individual must prevail over the sole interests of science or society (Council of Europe).

However, in the era of the "New Genetics," traditional informed consent faces the challenge of data complexity. Genetic information is not merely individual; it is also familial and collective, giving rise to the concept of genetic privacy (Anderson, 2004). Stephanie L. Anderson notes that sampling for research purposes can place subjects in a vulnerable position, because findings may affect family members who never provided consent. This

reality fuels debate over the need for more dynamic consent models where research participants retain the right to withdraw consent or impose specific limitations on future data use.

In addition, information asymmetry between healthcare providers and patients remains a major barrier to meaningful informed consent. In many cases, highly technical medical language is not fully understood by patients, making consent procedurally present but substantively weak (Faunce, 2005). Contemporary bioethics therefore stresses that informed consent should be treated as an ongoing communicative process, not merely as the signing of a formal document. Emphasizing education and genuine understanding becomes crucial to ensuring that individual sovereignty is maintained amid rapidly advancing and increasingly invasive biomedical interventions.

Genetic Non-Discrimination: Protecting Civil Rights and Social Justice

The principle of genetic non-discrimination aims to ensure that no individual is harmed or restricted in their fundamental rights solely on the basis of their genetic characteristics. As access to genomic mapping becomes easier, serious concerns arise regarding "genetic determinism," where a person's biological profile is used unfairly to predict their health future (UNESCO, 1997). This risks creating a new social class often described as the "genetically vulnerable" who may face discrimination in health insurance, employment access, or broader social rights (Ten et al., 2009).

The *Universal Declaration on the Human Genome and Human Rights* (1997) explicitly prohibits all forms of discrimination based on genetic characteristics that aim to violate human dignity (UNESCO, 1997). This prohibition is essential because genetic information is relatively fixed and not something an individual can readily change. Henk ten Have argues that genetic discrimination constitutes systemic injustice that must be resisted through strong regulation at both national and international levels (Ten et al., 2009). For example, insurers should not use genetic test results to set premiums or deny coverage, as doing so effectively punishes individuals for biological conditions beyond their control.

Beyond privacy and equal treatment, non-discrimination also raises questions of distributive justice in access to the benefits of biotechnological progress. Inequalities between developed and developing countries in access to gene therapies or precision medicine may widen the gap of global injustice. Sanyu Awori argues that international bioethics frameworks must ensure scientific progress is not captured by small elite groups, but distributed fairly to improve the quality of life for all humanity. Thus, strengthening genetic non-discrimination norms is not merely an individual privacy matter; it is a prerequisite for inclusive and just societies in the biotechnology century.

Comparative Study: Regulatory Fragmentation in ASEAN

Comparative legal analysis in ASEAN reveals significant differences in how member states manage genetic innovation, reflecting divergent national priorities between economic–scientific advancement and the protection of human rights.

Singapore: Legal Certainty and Governance of Biomedical Research

Singapore is widely regarded as having the most structured genetics regulation in ASEAN. Through the *Human Biomedical Research Act 2015* (HBRA), Singapore has established a highly technical framework designed to protect research subjects while facilitating innovation. The HBRA provides clear definitions of human biomedical research and imposes stringent requirements for appropriate consent, particularly for vulnerable groups such as individuals lacking mental capacity.

In addition, the Bioethics Advisory Committee (BAC) plays a central role in balancing Singapore's ambition to become a global "Biopolis" with ethical boundaries. The BAC regularly issues guidance addressing Ethical, Legal and Social Issues (ELSI) in genetic

testing, ensuring that clinical applications of genomic technologies are grounded in ethical justification before being implemented at scale.

Thailand: Integrating Ethics and Protecting Health Rights

Thailand adopts a more holistic approach by positioning genetic technologies under the broader umbrella of national welfare. Under the *National Health Act, B.E. 2550 (2007)*, health is defined broadly to include physical, mental, spiritual, and social dimensions, requiring health technologies to remain aligned with human dignity. In stem-cell research, Thailand has been active through initiatives such as the Stem Cell Network for the Asia Pacific region (SNAP), which aims to develop shared scientific and ethical guidelines to prevent uncontrolled commercialization of genetic materials (Issaragrisil, 2007).

Thailand's regulatory orientation tends to be more protective against exploitation risks, emphasizing that technological progress must generate equitable benefits and must not violate the social values held by communities (Go et al., 2014).

Indonesia: Health-System Modernization and Regulatory Gaps

Indonesia is currently in a dynamic regulatory transition in the health sector. The enactment of Law No. 17 of 2023 on Health represents a major step toward consolidating diverse health regulations, including the governance of health-technology transformation. While structurally adopting an omnibus approach, the operationalization of research ethics in Indonesia still relies heavily on national guidelines and standards for health research ethics. These guidelines stress risk mitigation through robust informed consent procedures, especially for subjects unable to provide consent independently, such as illiterate patients or other vulnerable groups.

Nevertheless, a significant gap remains in legal enforcement regarding cutting-edge genetic technologies such as germline editing. Current regulation still largely operates in the sphere of administrative ethics overseen by research ethics committees, meaning that sanctions for severe violations in genetic engineering may lack a specific criminal-law basis. Without an explicit human-rights-based legal framework at the statutory level governing the use of genetic information, Indonesia risks future legal complications and the emergence of genetic discrimination (Marici et al., 2025).

Table 1. Comparative Comparison of Genetic Regulations in ASEAN

Comparison Components	***Singapura***	***Thailand***	***Indonesia***
Main Legal Instruments	Human Biomedical Research Act 2015 (Singapore Statutes Online, 2026).	National Health Act, B.E. 2550 (ThaiLaws, 2007).	Law Number 17 of 2023 concerning Health.
Main Oversight Bodies	Bioethics Advisory Committee (BAC) Singapore.	National Health Commission & SNAP (Surapol Issaragrisil, 2007).	Ministry of Health & Indonesian Health Council (Law 17/2023).
Ethical Basis for Research	Ethical, Legal and Social Issues (ELSI) Consultation Paper 2005.	Holistic Health Concept (Physical, Mental, Spiritual, Social).	Code of Medical Ethics and Health Technology Transformation.[9]
Subject Protection	Very detailed regarding Informed Consent for	Focus on human dignity and the	General protection of patient rights

Comparison Components	*Singapura*	*Thailand*	*Indonesia*
	children and people with intellectual disabilities (HBRA Part 3).	right to health information (NHA Sections 7-8).	and personal data (Health Law & PDP Law).
Regulatory Status of Genetics	Comprehensive: Specifically regulates human biomedical research in one law.	Integrative: Embedded in the broader framework of the national health system.	Fragmentation: No specific law; regulations are scattered across various sectors.
Strength of Sanctions Against Abuse	High: Criminal sanctions and administrative fines are explicitly stated in the HBRA.	Moderate: Administrative sanctions and strict professional ethical guidelines.	Weaknesses: There is still a legal vacuum for sanctions against germ-line editing.

Source: Summary from various sources in sub-chapter 2.2

E. CONCLUSION

The integration of bioethical principles into international law is essentially a normative effort to ensure that the acceleration of biotechnology innovation does not diminish human dignity or fundamental rights. In international instruments, the meaning of bioethics, as affirmed in Article 1 of the Universal Declaration on Bioethics and Human Rights (2005), positions the application of medical and life sciences to humans as a domain that must simultaneously consider social, legal, and environmental dimensions, not simply scientific effectiveness or economic utility. This research findings reveal a significant regulatory gap in the ASEAN region: Singapore has developed a relatively progressive framework through its Bioethics Advisory Committee (BAC), which plays an active role in providing ethically based policy recommendations, while several other member states, including Indonesia, remain in a "grey zone" due to the lack of specific regulations related to biotechnology and genetic data protection. This situation creates long-term risks, particularly potential human rights violations through genetic discrimination, the commercialization of biological data without adequate consent, and weak privacy protections in the cross-border research and healthcare ecosystem. Based on these gaps, this research's recommendations point to two mutually reinforcing policy agendas. First, the establishment of a binding ASEAN Bioethics Framework to address cross-border mobility and intensified genomic research collaboration, while simultaneously preventing the unethical practice of "genetic tourism." This framework needs to translate universal principles into regional operational standards of respect for autonomy, truly informed consent, and the protection of privacy and confidentiality of genetic data. Second, the renewal of national legislation in Indonesia through regulations at the level of laws specifically governing biotechnology and the protection of individual genetic data, so that the state has a sufficiently strong instrument to guarantee the right to health and protect citizens from genetic discrimination and the exploitation of biological data. These two steps regional standardization and strengthening of domestic law position bioethics not as a "moral accessory" but as a governance architecture that ensures scientific progress aligns with the protection of human rights and dignity.

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