

“Human Genome Editing and Designer Genetics: Comparative Legal and Ethical Perspectives Under Indian and International Law”

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ABSTRACT

“यथा विज्ञानं शक्तिः, तथा धर्मः तस्य मर्यादा।”

Translation: Science is power, but ethics define its limits.
(Author’s adaptation)

Human genome editing and genetic selection technologies have transformed modern biomedical science by enabling targeted manipulation of human genetic material. Technologies such as CRISPR-Cas9 have created unprecedented opportunities for the prevention of hereditary diseases, therapeutic interventions, and reproductive choices. However, these advancements simultaneously raise significant legal, ethical, and human rights concerns relating to human dignity, equality, discrimination, reproductive autonomy, and bioethical governance. The absence of a comprehensive international consensus and the fragmented nature of domestic regulatory systems further complicate the legal landscape.

This research paper undertakes a comparative legal analysis of human genome editing and genetic selection under Indian and international law. It critically examines the legal and ethical dimensions associated with germline editing, somatic gene therapy, embryo research, and genetic selection practices. The paper evaluates international legal instruments including the UNESCO Universal Declaration on the Human Genome and Human Rights, the WHO Governance Framework for Human Genome Editing, and the Oviedo Convention. It also analyses the legal position in jurisdictions such as the United Kingdom, the United States, and China.

The paper further explores the Indian legal framework governing genome editing and genetic selection through constitutional principles, statutory provisions, regulatory guidelines, and judicial precedents. Particular emphasis is placed on the Assisted Reproductive Technology

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(Regulation) Act, 2021, the Surrogacy (Regulation) Act, 2021, the PCPNDT Act, 1994, and the Indian Council of Medical Research Guidelines.

The study concludes that India lacks a dedicated legislative framework regulating human genome editing and that existing laws are fragmented and insufficient to address emerging technological realities. It recommends the enactment of a specialized genome editing legislation, establishment of an independent bioethics authority, and harmonization of domestic law with evolving international standards.

Keywords: Human Genome Editing, Genetic Selection, CRISPR-Cas9, Bioethics, Indian Law, International Law, Human Rights, Germline Editing.

INTRODUCTION

The emergence of human genome editing technologies has revolutionized the field of biotechnology and modern medicine. Scientific innovations such as Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR-Cas9) have enabled researchers to alter DNA sequences with a level of precision previously unimaginable. These developments have created new possibilities for the treatment and prevention of genetic disorders. At the same time, they have raised serious legal, ethical, and policy concerns³.

Human genome editing refers to the process of altering the genetic structure of human cells through technological interventions. It can be broadly categorized into somatic genome editing and germline genome editing. Somatic editing affects only the treated individual and is generally considered less controversial because the genetic modifications are not inheritable. Germline editing, however, involves changes to reproductive cells or embryos, thereby allowing genetic modifications to be inherited by future generations.

Genetic selection involves the selection of embryos or genetic traits through reproductive technologies such as preimplantation genetic diagnosis (PGD). While such technologies may be used to prevent hereditary diseases, concerns arise when they are employed for non-therapeutic enhancement purposes, including sex selection, intelligence enhancement, or the creation of so-called “designer babies.”⁴ The legal implications of genome editing and genetic selection extend beyond the domain of science. They intersect with constitutional rights, human dignity, reproductive autonomy, public health, bioethics, and international human rights law. Legal questions concerning germline interventions, permissible limits of reproductive freedom, and the protection of future generations have become central to contemporary legal discourse.⁵

³ Jennifer Doudna and Emmanuelle Charpentier, ‘The New Frontier of Genome Engineering’ (2014) 346 *Science* 1258096.

⁴ Julian Savulescu and Nick Bostrom, *Human Enhancement* (Oxford University Press 2009).

⁵ César Palacios-González, ‘Human Dignity and Germline Editing’ (2019) 45 *Journal of Medical Ethics* 1.

The global legal response to genome editing remains fragmented. International instruments such as the UNESCO Universal Declaration on the Human Genome and Human Rights and the Oviedo Convention attempt to establish ethical boundaries⁶, yet they largely operate as soft law mechanisms. Domestic legal systems also differ considerably⁷. The United Kingdom adopts a regulated permissive approach under the Human Fertilisation and Embryology Act, while the United States relies heavily on administrative oversight⁸. China, following the controversial He Jiankui incident involving genetically edited babies, introduced stricter regulatory measures⁹.

In India, there is no dedicated legislation regulating human genome editing. Existing legal governance is dispersed across constitutional provisions, medical regulations, and reproductive technology laws. Although guidelines issued by the Indian Council of Medical Research (ICMR) and statutory frameworks such as the PCPNDT Act attempt to regulate aspects of reproductive genetics, significant regulatory gaps persist.¹⁰

This research paper seeks to critically examine the comparative legal framework governing human genome editing and genetic selection under Indian and international law. It analyses the adequacy of current legal mechanisms and proposes reforms to ensure that scientific advancement remains consistent with ethical principles and constitutional values.

This paper argues that while genome editing technologies possess transformative therapeutic potential, the absence of binding international standards and the fragmented nature of Indian regulation create serious constitutional, ethical, and human rights concerns. The study contends that India requires a specialized legislative framework balancing scientific innovation with constitutional morality, human dignity, and bioethical accountability.

RESEARCH METHODOLOGY

This study adopts a doctrinal and comparative legal research methodology. The research primarily relies upon primary legal sources including constitutional provisions, statutes, international conventions, declarations, regulatory guidelines, and judicial decisions. Secondary sources such as books, journal articles, reports of international organizations, and academic commentaries have also been utilized.

⁶ Convention on Human Rights and Biomedicine (Oviedo Convention), 1997, art 13.

⁷ UNESCO Universal Declaration on the Human Genome and Human Rights, 1997.

⁸ Human Fertilisation and Embryology Act 1990 (UK); Sheila McLean, 'Regulating Genetic Technologies' (2018) 12 *Medical Law Review* 45.

⁹ Sheila McLean, 'Regulating Genetic Technologies' (2018) 12 *Medical Law Review* 45.

¹⁰ Indian Council of Medical Research, *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* (2017); Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act 1994.

The comparative method is employed to evaluate the legal frameworks governing genome editing in India, the United Kingdom, the United States, and China. The research also analyses international bioethical standards developed by UNESCO and the World Health Organization.

The study adopts both analytical and descriptive approaches to evaluate existing legal frameworks. It critically examines the strengths and weaknesses of existing regulatory frameworks and identifies areas requiring legislative reform. The study further adopts an interdisciplinary approach due to the intersection of genome editing with constitutional law, bioethics, public health, and international human rights law. Comparative analysis has been undertaken to evaluate diverse regulatory approaches adopted in the United Kingdom, the United States, China, and India. The empirical survey was conducted through structured questionnaire distributed online¹¹.

Empirical Analysis and Public Perception

In addition to doctrinal and comparative legal analysis, an empirical survey titled “*Public Perception on Human Genome Editing and Genetic Selection: A Legal Study*” was conducted to understand societal attitudes towards genome editing technologies and their regulation in India. The survey involved 58 respondents from diverse educational and professional backgrounds. The findings reflected increasing public awareness regarding human genome editing and the ethical concerns associated with genetic intervention technologies.

Survey Findings	Percentage of Respondents
Support therapeutic genome editing for disease prevention	77.6%
Support enhancement-oriented genome editing	32.7%
Believe India lacks adequate legal regulation	84.5%
Express concerns regarding genetic inequality and discrimination	72.4%
Support enactment of dedicated genome editing legislation	89.6%

Source: Empirical Survey Conducted by Author (2026).

¹¹ Author’s empirical survey conducted through structured online questionnaires (2026).

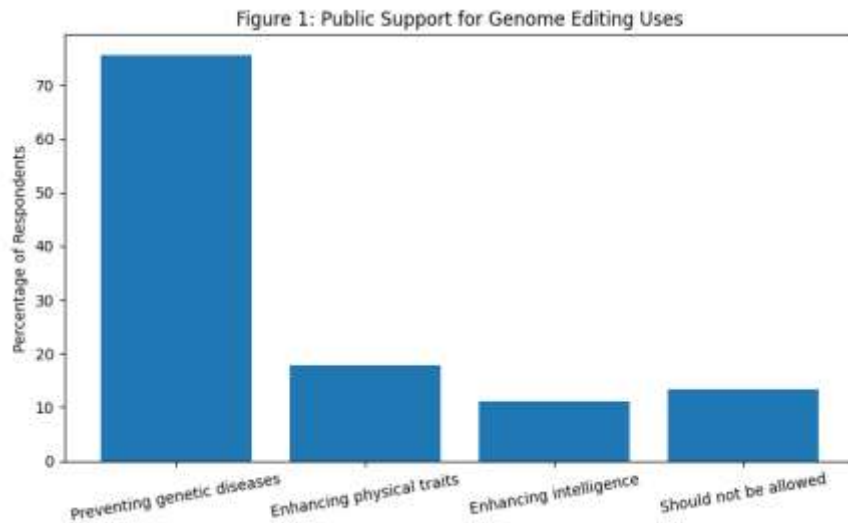


Figure 1: Public Support for Therapeutic and Enhancement Uses of Genome Editing
 Source: Empirical Survey Conducted by Author (2026)

A majority of respondents supported the use of genome editing for therapeutic purposes, particularly for the prevention of serious hereditary diseases. However, comparatively fewer respondents supported the use of such technologies for enhancement purposes, including increasing intelligence, physical abilities, or other non-medical traits.

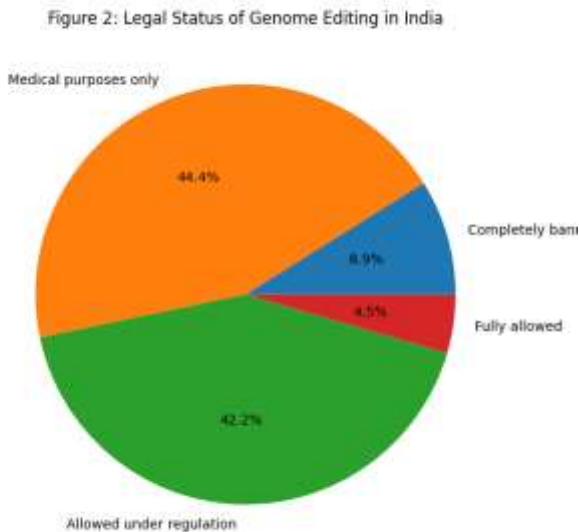


Figure 2: Public Opinion Regarding Legal Regulation of Genome Editing in India
 Source: Empirical Survey Conducted by Author (2026)

The survey further revealed that many participants believed that India presently lacks a comprehensive legal framework capable of effectively regulating genome editing technologies. Several respondents emphasized the necessity of introducing strict statutory regulation and ethical oversight mechanisms similar to those adopted in developed jurisdictions. Concerns were also expressed regarding the possibility of social inequality and genetic discrimination arising from unrestricted access to genetic enhancement technologies, thereby raising important constitutional concerns relating to equality and non-discrimination under Article 14 of the Constitution of India. The survey additionally indicated strong public support for enforceable legal standards, ethical accountability, and penalties against unauthorized genetic experimentation. Overall, the empirical findings demonstrate that while society recognizes the therapeutic potential of genome editing, significant apprehension continues to exist regarding ethical misuse, commercialization, and inadequate legal regulation in India. Approximately 78% of respondents supported therapeutic genome editing for prevention of hereditary diseases, whereas only 32% supported enhancement-oriented genetic interventions.

CONCEPTUAL FRAMEWORK OF HUMAN GENOME EDITING AND GENETIC SELECTION

Human Genome Editing

Human genome editing refers to deliberate modifications made to an organism's DNA through scientific technologies. Recent developments in molecular biology have enabled scientists to edit genes with remarkable precision. Among these technologies, CRISPR-Cas9 has emerged as the most significant due to its efficiency, affordability, and accuracy. Genome editing may be therapeutic or enhancement-oriented. Therapeutic editing seeks to cure or prevent diseases such as sickle-cell anaemia, cystic fibrosis, or Huntington's disease.¹² Enhancement-oriented editing aims to improve human characteristics such as intelligence, physical ability, or appearance.

Somatic Genome Editing

Somatic genome editing involves modifications in non-reproductive cells. The changes affect only the individual receiving treatment and are not passed to future generations. Most legal systems consider somatic editing permissible for therapeutic purposes subject to regulatory approval.

¹² Jennifer Doudna and Emmanuelle Charpentier, 'The New Frontier of Genome Engineering' (2014) 346 Science 1258096.

Germline Genome Editing

Germline editing affects embryos, sperm, or eggs. Genetic modifications become inheritable and may permanently alter the human gene pool. Germline editing remains highly controversial due to concerns relating to ethics, safety, and intergenerational consequences¹³.

Genetic Selection

Genetic selection refers to the process of selecting embryos or gametes based on specific genetic characteristics. Technologies such as preimplantation genetic diagnosis allow prospective parents to screen embryos for genetic disorders before implantation. Although genetic selection may reduce hereditary diseases, it also raises constitutional concerns regarding discrimination, eugenics, and commodification of human life. Ethical debates intensify when genetic selection is used for non-medical purposes such as sex selection or enhancement.

ETHICAL ISSUES IN HUMAN GENOME EDITING

Human Dignity

Human dignity constitutes one of the central ethical concerns in genome editing debates. Critics argue that altering the human germline may undermine the intrinsic value of human beings by transforming reproduction into a process of genetic design. The possibility of creating “designer babies” raises fears regarding commodification and loss of individuality. International human rights instruments consistently emphasize the protection of human dignity. The UNESCO Universal Declaration on the Human Genome and Human Rights recognizes the human genome as the heritage of humanity¹⁴.

Equality and Non-Discrimination

Genome editing technologies may intensify social inequality. Access to expensive genetic enhancements may become limited to wealthy individuals, thereby creating genetic stratification within society. Concerns also arise regarding discrimination against persons with disabilities if society increasingly values genetically “enhanced” traits. Genome editing and genetic screening technologies also create serious concerns relating to genetic discrimination. Individuals may face unequal treatment in employment, insurance, education, and healthcare based upon their genetic characteristics or predisposition to disease. Such discrimination becomes particularly problematic because genetic traits are inherited rather than voluntarily acquired. Unlike lifestyle choices, individuals possess no control over their inherited genetic composition. The misuse of genetic information by employers, insurers, or public authorities may therefore violate constitutional principles of equality, dignity, and non-discrimination.

¹³ WHO Governance Framework for Human Genome Editing, 2021.

¹⁴ UNESCO Universal Declaration on the Human Genome and Human Rights (1997).

Concerns have also emerged regarding the creation of a potential “genetic underclass,” where access to opportunities becomes dependent upon biological traits rather than individual merit.

Genetic Privacy and Informational Autonomy

The increasing use of genome sequencing and genetic testing raises significant concerns regarding privacy and informational autonomy. Genetic data is uniquely sensitive because it reveals not only personal medical information but also hereditary characteristics affecting biological relatives and future generations. Unauthorized disclosure or misuse of genetic information may expose individuals to discrimination, social stigma, or economic exclusion. The right to privacy recognized under Article 21 of the Constitution of India¹⁵ in *Justice K.S. Puttaswamy v. Union of India*¹⁶ assumes particular significance in the context of genome editing governance. Genetic privacy therefore requires robust legal safeguards relating to consent, storage, access, and disclosure of genetic data.

Eugenics

The history of eugenics demonstrates the dangers associated with attempts to engineer human populations. Genetic selection for preferred traits may revive discriminatory ideologies that seek to define socially desirable characteristics.

Rights of Future Generations

Germline editing affects future generations who cannot consent to genetic modifications. Legal scholars debate whether present generations possess moral authority to irreversibly alter the genetic composition of future persons¹⁷. Germline genome editing raises profound intergenerational concerns because genetic modifications may permanently alter the biological inheritance of future persons without their consent. Legal and ethical scholars therefore debate whether present generations possess the moral or constitutional authority to irreversibly modify the genetic composition of humanity itself.

INTERNATIONAL LEGAL FRAMEWORK GOVERNING HUMAN GENOME EDITING

UNESCO Universal Declaration on the Human Genome and Human Rights, 1997

The UNESCO Universal Declaration on the Human Genome and Human Rights represents one of the earliest international attempts to regulate genetic technologies. The Declaration recognizes the human genome as symbolic of the heritage of humanity. Article 11 prohibits

¹⁵ Constitution of India, art 21.

¹⁶ *Justice K.S. Puttaswamy v Union of India (2017) 10 SCC 1.*

¹⁷ Ronald Dworkin, *Life's Dominion* (Harper Collins 1993).

practices contrary to human dignity, including reproductive cloning of human beings. The Declaration emphasizes informed consent, confidentiality, and protection against genetic discrimination. However, the Declaration lacks binding legal force. Although international declarations concerning the human genome establish important ethical principles, most of these instruments operate as non-binding soft law frameworks lacking effective enforcement mechanisms. Their implementation remains dependent upon domestic political will and legislative incorporation by individual states. Consequently, substantial inconsistencies persist in national approaches toward genome editing and genetic experimentation. Its implementation depends upon domestic legislation adopted by individual states¹⁸.

WHO Governance Framework for Human Genome Editing

The World Health Organization established an Expert Advisory Committee to develop governance standards for genome editing. The WHO framework emphasizes transparency, ethical review, public participation, and international cooperation. The WHO recommends that no clinical application of human germline editing should proceed until scientific, ethical, and societal concerns are adequately addressed¹⁹.

Oviedo Convention

The Convention on Human Rights and Biomedicine, commonly known as the Oviedo Convention, is the most comprehensive binding international instrument governing biomedical interventions.

Article 13 permits interventions seeking preventive, diagnostic, or therapeutic purposes only if they are not intended to introduce modifications into the genome of descendants. Thus, the Convention effectively prohibits inheritable germline editing²⁰.

International Human Rights Law

Genome editing implicates various human rights including:

1. Right to life
2. Right to health
3. Right to privacy
4. Right to equality
5. Right to human dignity

¹⁸ UNESCO Universal Declaration on the Human Genome and Human Rights (1997) art 11.

¹⁹ WHO Governance Framework for Human Genome Editing (2021).

²⁰ Convention on Human Rights and Biomedicine (Oviedo Convention) 1997, art 13.

International covenants such as the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights provide a broader normative framework for evaluating genome editing practices²¹.

COMPARATIVE ANALYSIS OF SELECT JURISDICTIONS

United Kingdom

The United Kingdom possesses one of the most developed governance structures governing reproductive technologies. The United Kingdom model demonstrates that scientific innovation may coexist with strong institutional oversight and bioethical accountability²².

Human Fertilisation and Embryology Act, 1990

The Human Fertilisation and Embryology Act regulates embryo research, assisted reproduction, and genetic interventions. The Human Fertilisation and Embryology Authority (HFEA) supervises reproductive technologies and grants licenses for embryo research. The United Kingdom permits limited embryo research subject to strict regulatory oversight. Mitochondrial replacement therapy has also been legalized under controlled conditions²³. However, implantation of genetically modified embryos for reproductive purposes remains prohibited.

United States

The United States does not possess a comprehensive federal statute governing genome editing. Regulation occurs through agencies such as the Food and Drug Administration (FDA) and the National Institutes of Health (NIH)²⁴. Federal funding restrictions prohibit certain forms of embryo research. Nevertheless, private research activities remain relatively less regulated compared to European jurisdictions. The absence of a uniform legal framework has generated criticism regarding regulatory inconsistency. The decentralized American framework illustrates the limitations of agency-based governance in the absence of comprehensive federal legislation²⁵.

²¹ International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171; International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3.

²² Human Fertilisation and Embryology Act 1990 (UK).

²³ Human Fertilisation and Embryology Act 1990 (UK); Human Fertilisation and Embryology Authority, 'Genome Editing and Human Fertilisation Regulation' (HFEA).

²⁴ John Harris, *Enhancing Evolution* (Princeton University Press 2007).

²⁵ National Institutes of Health, 'NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules'.

China

China attracted international controversy following the 2018 announcement by scientist He Jiankui that genetically edited babies had been born using CRISPR technology. The incident triggered widespread condemnation and prompted the Chinese government to strengthen regulatory oversight. China subsequently introduced stricter biosecurity laws and criminal penalties for unauthorized genetic experimentation²⁶. China's Biosecurity Law emphasizes state supervision, ethical review mechanisms, and penalties for illegal biomedical research. China's regulatory reforms reflect a reactive model of governance emerging after ethical failures exposed institutional weaknesses.

The He Jiankui Controversy

In 2018, the field of human genome editing became the subject of global controversy when Chinese scientist He Jiankui announced that genetically edited twin babies had been born through the use of CRISPR-Cas9 technology. According to reports, the genes of human embryos were altered prior to birth with the objective of making the children resistant to HIV infection. The announcement prompted widespread criticism from scientists, legal scholars, and bioethicists across the world.²⁷ Serious concerns were raised regarding the absence of adequate ethical supervision, lack of scientific transparency, and uncertainty surrounding the long-term consequences of germline modification. Questions were also raised regarding the validity of informed consent obtained from the parents participating in the experiment. Since germline editing permanently affects future generations, many experts argued that such experimentation should not proceed without comprehensive legal regulation and established scientific safeguards. The incident demonstrated how rapidly advancing genetic technologies may outpace existing legal and ethical frameworks. Chinese authorities subsequently initiated legal proceedings against He Jiankui and imposed criminal penalties for unlawful medical practices. The controversy significantly influenced global debates concerning bioethics, scientific accountability, and the urgent need for effective international governance mechanisms relating to human genome editing.

INDIAN LEGAL FRAMEWORK GOVERNING HUMAN GENOME EDITING AND GENETIC SELECTION

Constitutional Framework

Article 21: Right to Life and Personal Liberty

²⁶ Arvind Narrain, 'Bioethics and Constitutionalism in India' (2020) *Indian Journal of Medical Ethics* 67.

²⁷ Sheila McLean, 'Regulating Genetic Technologies' (2018) 12 *Medical Law Review* 45; WHO Governance Framework for Human Genome Editing (2021).

Article 21 of the Constitution of India²⁸ has been interpreted expansively by the Supreme Court to include reproductive autonomy, privacy, health, and dignity. In *Suchita Srivastava v. Chandigarh Administration*²⁹, the Supreme Court recognized reproductive choice as a dimension of personal liberty. Genome editing and genetic selection technologies intersect directly with reproductive autonomy. The right to privacy recognized in *Justice K.S. Puttaswamy v. Union of India*³⁰ further strengthens protection of genetic information and bodily autonomy. Similar concerns relating to reproductive autonomy and reproductive decision-making were examined by the European Court of Human Rights in *Evans v United Kingdom*³¹, where the Court considered the balance between individual reproductive rights and competing state interests.

Article 14: Equality Before Law

Genetic discrimination may violate Article 14 of the Constitution of India³² by creating unequal treatment based on genetic characteristics. The possibility of selective enhancement technologies may also produce structural inequalities.

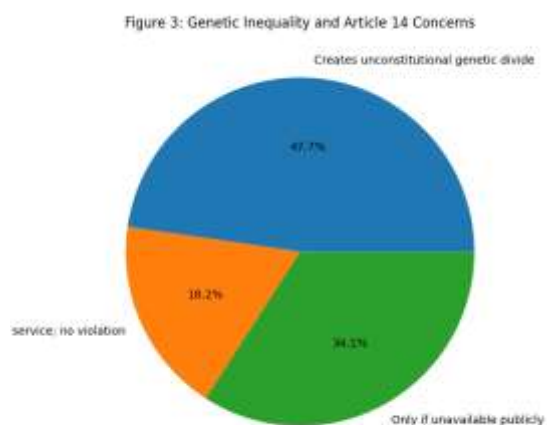


Figure 3: Public Concerns Regarding Genetic Inequality and Article 14
Source: Empirical Survey Conducted by Author (2026)

The risks associated with genetic discrimination may acquire greater significance in India due to existing social and economic inequalities. Unequal access to advanced genetic technologies may intensify structural disparities and create new forms of exclusion based upon biological

²⁸ Constitution of India, art 21.

²⁹ *Suchita Srivastava v Chandigarh Administration* (2009) 9 SCC 1.

³⁰ *Justice K.S. Puttaswamy v Union of India* (2017) 10 SCC 1.

³¹ *Evans v United Kingdom* (2007) ECHR 264.

³² Constitution of India, art 14.

characteristics. These concerns become particularly serious within a society already affected by unequal healthcare access and socio-economic stratification.

Article 19: Freedom of Profession, Expression, and Scientific Research

Scientific research and medical innovation may also receive protection under Article 19 of the Constitution of India³³. Scientists, doctors, and research institutions have the freedom to pursue scientific advancement and professional practice. However, these freedoms are not absolute and may be reasonably restricted in the interest of public health, morality, and ethical oversight. Genome editing, especially germline modification and genetic enhancement, therefore requires proper legal regulation to prevent misuse and protect human dignity and societal interests.

STATUTORY FRAMEWORK IN INDIA

Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994

The PCPNDT Act prohibits sex selection before and after conception. The legislation was enacted primarily to combat female foeticide and gender discrimination. Although the Act addresses misuse of reproductive technologies, it does not comprehensively regulate genome editing³⁴.

Assisted Reproductive Technology (Regulation) Act, 2021

The Assisted Reproductive Technology (Regulation) Act regulates fertility clinics and assisted reproductive procedures in India. The Act establishes registration requirements and standards for ART clinics. However, it does not directly address genome editing technologies³⁵.

Surrogacy (Regulation) Act, 2021

The Surrogacy (Regulation) Act regulates surrogacy arrangements and seeks to prevent exploitation of women. It indirectly intersects with genetic technologies through regulation of reproductive procedures³⁶.

New Drugs and Clinical Trials Rules, 2019

Gene therapy products may fall within the scope of clinical trial regulations under Indian law. Regulatory approval is required for biomedical experimentation involving human participants.

³³ Constitution of India, art 19.

³⁴ Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994.

³⁵ Assisted Reproductive Technology (Regulation) Act, 2021.

³⁶ Surrogacy (Regulation) Act 2021.

ICMR Guidelines

The Indian Council of Medical Research has issued ethical guidelines relating to biomedical research and assisted reproductive technologies. ICMR guidelines³⁷ generally prohibit germline gene therapy due to bioethical dilemmas. However, guidelines lack the enforceability of statutory law.

Genetic Data Protection and Privacy

India presently lacks a comprehensive statutory framework specifically regulating genetic data protection. The increasing use of genome sequencing and genetic testing raises constitutional concerns relating to storage, access, processing, and disclosure of highly sensitive genetic information. Although the Digital Personal Data Protection Act, 2023³⁸ provides general data protection principles, it does not specifically address the unique risks associated with genetic data. In this context, constitutional principles of privacy, informational autonomy, and bodily integrity become increasingly significant in regulating genome editing technologies.

JUDICIAL APPROACH IN INDIA

Indian courts have not yet directly adjudicated upon genome editing. Nevertheless, constitutional jurisprudence concerning privacy, reproductive rights, and medical ethics provides guidance.

Suchita Srivastava v. Chandigarh Administration

The Supreme Court recognized reproductive autonomy as an essential aspect of personal liberty under Article 21³⁹

Justice K.S. Puttaswamy v. Union of India

The right to privacy judgment recognized informational privacy and bodily autonomy. Genetic data protection emerges as a critical issue in genome editing governance⁴⁰.

³⁷ Indian Council of Medical Research, *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants* (2017).

³⁸ Digital Personal Data Protection Act 2023 (India).

³⁹ *Suchita Srivastava v Chandigarh Administration* (2009) 9 SCC 1.

⁴⁰ *Justice K.S. Puttaswamy v Union of India* (2017) 10 SCC 1.

Devika Biswas v. Union of India

The Court emphasized informed consent and reproductive dignity in public health interventions. These decisions collectively support a constitutional framework grounded in dignity, autonomy, and informed consent⁴¹.

COMPARATIVE LEGAL ANALYSIS**Regulatory Approaches**

The United Kingdom adopts a structured regulatory model based upon statutory oversight and licensing mechanisms. The Human Fertilisation and Embryology Authority performs centralized supervision. The United States follows a decentralized administrative model emphasizing agency regulation rather than comprehensive legislation. China employs a state-controlled oversight model with stringent governmental oversight following the He Jiankui incident. India, by contrast, lacks a specialized legal framework governing genome editing. Existing regulations are fragmented and primarily focused upon reproductive technologies rather than genetic interventions.

Germline Editing

Most jurisdictions prohibit reproductive germline editing due to ethical and safety concerns.

1. United Kingdom – Research permitted under regulation; reproductive use prohibited.
2. United States – Clinical germline editing effectively restricted.
3. China – Strictly regulated with criminal liability.
4. India – No explicit legislation; governed indirectly through guidelines.

Genetic Selection

India prohibits sex selection under the PCPNDT Act. However, broader genetic enhancement and embryo selection remain inadequately regulated. The United Kingdom permits preimplantation genetic diagnosis under controlled conditions for preventing serious genetic diseases. The United States permits broader reproductive autonomy subject to limited restrictions.

Human Rights Perspective

International law consistently emphasizes dignity, informed consent, and non-discrimination. However, the absence of binding global standards results in inconsistent domestic implementation. India's constitutional jurisprudence provides a strong normative basis for

⁴¹ Devika Biswas v Union of India (2016) 10 SCC 726.

protecting reproductive autonomy and privacy. Yet, legislative mechanisms remain underdeveloped.

CHALLENGES IN REGULATING HUMAN GENOME EDITING

Regulatory Vacuum

Rapid scientific advancements often outpace legal regulation. Many jurisdictions struggle to formulate comprehensive laws capable of addressing emerging technologies.

Ethical Uncertainty

Disagreements persist regarding the ethical acceptability of germline interventions and enhancement technologies.

Commercialization of Genetics

Private biotechnology corporations increasingly influence genetic research and reproductive services. Questions have also been raised regarding the patentability of human genes, ownership of genetic information, and monopolization of biomedical innovation. Critics argue that the human genome constitutes the common heritage of humanity and should not become subject to excessive proprietary control. Commercial exploitation of genetic technologies without adequate ethical oversight may undermine equitable access to healthcare and scientific benefits. Commercial interests may undermine ethical safeguards⁴².

Genetic Discrimination

Employers, insurers, and educational institutions may misuse genetic information to discriminate against individuals.

International Inconsistency

Differences in national regulation create the possibility of “genetic tourism,” whereby individuals seek permissive jurisdictions for prohibited procedures.

FINDINGS

1. Human genome editing possesses transformative therapeutic potential but raises profound ethical and legal concerns.
2. International regulation remains fragmented and largely dependent upon soft law instruments.

⁴² George J Annas, *Genetic Privacies: Towards a Genetics Bill of Rights* (Yale University Press 1995).

3. The Oviedo Convention represents the strongest international legal restriction on inheritable germline modification.
4. The United Kingdom possesses the most structured regulatory model among major jurisdictions.
5. India lacks a dedicated statutory framework regulating genome editing and genetic selection.
6. Existing Indian laws indirectly regulate reproductive technologies but fail to address contemporary genetic interventions comprehensively.
7. Constitutional principles of dignity, privacy, and reproductive autonomy provide a normative foundation for future regulation.
8. Absence of clear legal standards may lead to unethical experimentation and exploitation.

SUGGESTIONS AND RECOMMENDATIONS

Enactment of Dedicated Genome Editing Legislation

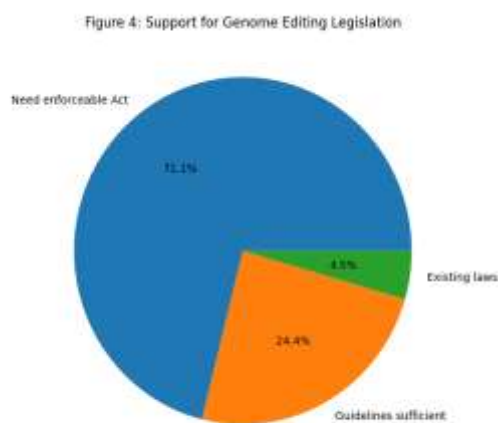


Figure 4: Support for Statutory Regulation
Source: Empirical Survey Conducted by Author (2026)

India should enact a specialized Human Genome Editing Regulation Act addressing:

1. Permissible research activities
2. Prohibited practices
3. Licensing procedures
4. Ethical review mechanisms
5. Criminal liability
6. Data protection safeguards

Establishment of National Bioethics Authority

An independent statutory authority should supervise genome editing research, reproductive technologies, and genetic data protection.

Regulation of Germline Editing

India should expressly prohibit clinical germline editing until scientific safety and constitutional concerns are resolved.

Protection Against Genetic Discrimination

Comprehensive anti-discrimination legislation should prohibit misuse of genetic information by employers, insurers, and public authorities.

International Cooperation

Global harmonization of bioethical standards is necessary to prevent regulatory arbitrage and unethical experimentation.

Strengthening Informed Consent

Robust consent procedures should be mandated for all genetic interventions and biomedical research activities.

CONCLUSION

Human genome editing and genetic selection technologies represent one of the most significant scientific developments of the twenty-first century. While these technologies possess extraordinary potential for preventing genetic diseases and improving human health, they simultaneously generate serious ethical, constitutional, and legal concerns.

The comparative analysis demonstrates that international and domestic legal frameworks continue to remain fragmented and inconsistent. International instruments such as the UNESCO Declaration and WHO Governance Framework establish important ethical principles but lack binding enforceability. Jurisdictions such as the United Kingdom have developed sophisticated regulatory mechanisms, whereas countries like India continue to rely upon fragmented statutory provisions and non-binding guidelines.

India's constitutional jurisprudence concerning dignity, privacy, and reproductive autonomy provides a strong normative basis for regulating genome editing. However, the absence of comprehensive legislation creates uncertainty and regulatory gaps. A balanced regulatory framework is therefore essential. Such a framework must encourage responsible scientific

innovation while simultaneously safeguarding human dignity, equality, informed consent, and the interests of future generations. Genome editing should not become a tool for social inequality, discrimination, or commercial exploitation. Advances in biotechnology increasingly challenge traditional legal understandings of identity, autonomy, equality, and human dignity. Genome editing therefore represents not merely a scientific development, but a constitutional and civilizational question concerning the limits of human intervention into biological inheritance itself⁴³. The future challenge before constitutional democracies is not merely whether genome editing should be permitted, but whether legal systems possess sufficient ethical and institutional capacity to regulate technologies capable of altering the biological future of humanity.

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⁴³ Sheila Jasanoff, *Reframing Rights: Bio constitutionalism in the Genetic Age* (MIT Press 2011).

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1. Constitution of India.
2. Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act 1994.
3. Assisted Reproductive Technology (Regulation) Act 2021.
4. Surrogacy (Regulation) Act 2021.
5. New Drugs and Clinical Trials Rules 2019.
6. Digital Personal Data Protection Act 2023.

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3. *Devika Biswas v. Union of India* (2016) 10 SCC 726.
4. *Evans v. United Kingdom* (2007) ECHR 264.