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https://doi.org/10.47353/lawpass.v3i2.117

Regulation of CRISPR-Mediated Genome Editing in Humans: An Indian Perspective

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Abstract

November 2025 marked seven years since a Chinese biophysicist declared having used the controversial CRISPR technology to produce the world's first genome-edited baby. Much before this unprecedented application of CRISPR, the scientific community has been rallying for an international moratorium on heritable genome editing in humans. Although global consensus makes room for uninheritable gene therapies, but the regulatory approvals for CRISPR-mediated gene therapies have only just begun to be considered. What lies ahead is an uphill battle for responsible and uniform policymaking, as well as public acceptance of novel gene-editing techniques in the backdrop of localized social, political, and religious affiliations. This paper aims to analyze several legal frameworks governing the use of CRISPR technology in humans, with a particular focus on Indian biotechnology regulations. It further identifies crucial shortcomings in the existing biomedical policies and carves a pathway for better regulation and widespread acceptance towards this groundbreaking technology.

Keywords: CRISPR, germline, genome editing, heritable, gene therapy, regulation.

Introduction

Clustered regularly interspaced short palindromic repeats (CRISPR) together with Cas (CRISPR-associated) proteins form the adaptive immune system in bacteria and archaea.[1] Interest in this prokaryotic defense system peaked when its mechanism was repurposed as a gene-editing tool, most notably by Emmanuelle Charpentier and Jennifer A. Doudna in the year 2012; a feat that earned them the prestigious Nobel Prize in Chemistry.[2] This novel genome editing tool has since surpassed similar technologies including zinc-finger nucleases (ZFNs)

[1] Josaine Garneu et al., *The CRISPR/Cas Bacterial Immune System Cleaves Bacteriophage and Plasmid DNA*, 468 NATURE 67 (2010).

[2] Katherine Wu, Carl Zimmer & Elian Peltier, *Nobel Prize in Chemistry Awarded to 2 Scientists for Work on Genome Editing,* N.Y. TIMES (Oct. 7, 2020), https://www.nytimes.com/2020/10/07/science/nobel-prize-chemistry-crispr.html.

Received: May 22, 2026 | **Revised:** Jun 7, 2026 | **Accepted:** Juni 25, 2026 | **Publication:** June 30, 2026

and transcription activator-like effector nucleases (TALENs) and has revolutionized the field of biotechnology.[3]

Since its advent, CRISPR technology has found crucial applications in eukaryotic genome editing, pharmaceutical development, gene expression, diagnostics, and the prevention and treatment of cancers as well as genetic and infectious diseases.[4] It can be used to carry out gene-editing in germline cells (sperm, eggs or embryos) as well as in somatic cells.[5] In somatic gene editing, any off-target mutations are confined to the treated individual and are not inherited. Unlike somatic editing, germline editing leads to heritable genomic changes as the edited gene is replicated in all cells of the individual. It is also noteworthy that somatic cell therapies have been studied, tested and highly regulated for at least two decades.[6] As such, several clinical trials for the use of CRISPR in treating hereditary blood disorders,[7] cancers,[8] diabetes,[9] blindness,[10] high cholesterol,[11] etc. are underway and have shown great promise. However, despite the revolutionary potential of CRISPR, concerns about its socio-ethical ramifications persist, including fears of intergenerational consequences and unforeseeable detriment to societies due to heritable genome editing.[12] Debates surrounding CRISPR intensified after Chinese researcher He Jiankui announced having genetically modified viable human embryos for the first time ever.[13] And although He faced criminal action,[14] apprehensions about the same repeating itself

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[3] Congting Guo et al., *Off-Target Effects in CRISPR/Cas9 Gene Editing*, 11 FRONT. BIOENG. BIOTECHNOL. (2023), https://doi.org/10.3389/fbioe.2023.1143157.

[4] Abozar Ghorbani et al., *A Short Overview of CRISPR-Cas Technology and Its Application in Viral Disease Control*, 30(3) TRANSGENIC RES. 221 (2021).

[5] Emma Johnson et al., *Somatic Genome Editing – An Overview*, PHG FOUND. (May 2019), https://www.phgfoundation.org/media/211/download/policy-briefing-somatic-genome-editing-overview.pdf?v=1&inline=1.

[6] Mary Todd Bergman, *Perspectives on Gene Editing*, HARV. GAZETTE (Jan. 9, 2019), https://news.harvard.edu/gazette/story/2019/01/perspectives-on-gene-editing/.

[7] Kai Kupferschmidt, *Gene-Editing Summit Touts Sickle Cell Success, While Questions on Embryo Editing Linger*, SCIENCE (Mar. 13, 2023), https://www.science.org/content/article/gene-editing-summit-touts-sickle-cell-success-while-questions-embryo-editing-linger.

[8] Dimitrios Stefanoudakis et al., *The Potential Revolution of Cancer Treatment with CRISPR Technology*, 15 CANCERS 1813 (2023).

[9] Yan Cheng, Haiyang Wang & Mo Li, *The Promise of CRISPR/Cas9 Technology in Diabetes Mellitus Therapy: How Gene Editing Is Revolutionizing Diabetes Research and Treatment*, 37 J. DIABETES COMPLICATIONS 108524 (2023).

[10] Eileen Bailey, *How CRISPR Gene Editing May Help Reverse Vision Loss*, HEALTHLINE (Mar. 17, 2023), https://www.healthline.com/health-news/how-crispr-gene-editing-may-help-reverse-vision-loss#:~:text=The%20scientists%20used%20the%20CRISPR,normal%20electrical%20responses%20to%20light.

[11] Jessica Hamzelou, *CRISPR for High Cholesterol: 10 Breakthrough Technologies 2023*, MIT TECH. REV. (Jan. 9, 2023), https://www.technologyreview.com/2023/01/09/1064857/crispr-high-cholesterol-10-breakthrough-technologies-2023/.

[12] Françoise Baylis et al., *Human Germline and Heritable Genome Editing: The Global Policy Landscape*, 3 CRISPR J. 365 (2020).

[13] Rob Stein, *Chinese Scientist Says He's First to Create Genetically Modified Babies Using CRISPR*, NPR (Nov. 26, 2018), https://www.npr.org/sections/health-shots/2018/11/26/670752865/chinese-scientist-says-hes-first-to-genetically-edit-babies.

[14] Dana Goodyear, *Dangerous Designs: Gene Editing Gives Us Transformative Powers. But Should We Use Them?*, NEW YORKER (Sept. 2, 2023), https://www.newyorker.com/magazine/2023/09/11/the-transformative-alarming-power-of-gene-editing.

are on the rise. Reflecting on the said sentiment, the 2023 International Summit on Human Genome Editing concluded: "*heritable human genome editing remains unacceptable at this time*".[15]

According to various experts, the use of CRISPR for eugenics and enhancement beyond therapeutic motives, also poses a threat to the human gene pool.[16] Recent studies reaffirm cynicism around heritable germline editing, evincing that early human embryos are demonstrably deficient in DNA repair,[17] and that CRISPR-based gene therapies could trigger cancers and cause greater genetic damage than previously anticipated.[18] Current regulatory frameworks do not sufficiently address the heritability of germline changes,[19] thus necessitating further scientific and ethicolegal deliberations on the use of CRISPR in human genome editing. Moreover, approvals by the United Kingdom and the United States for "Casgevy", the world's first licensed CRISPR-based gene therapy for sickle cell disease and beta-thalassemia,[20,21] signal a likely surge in regulatory approvals for CRISPR therapies in times to come.[22] Consequently, developing nations like India are on the cusp of deciding major policy changes regarding the usage of CRISPR-mediated gene therapies in humans.

It is against this backdrop that the present paper examines Indian laws on gene-editing technologies within the context of international standards, domestic laws in various jurisdictions, and the global scientific consensus. It further assesses the sufficiency of the existing regulatory landscape to deal with the imminent commercialization of CRISPR-based gene therapies and proposes crucial changes in existing laws to better regulate novel genome editing techniques.

International Standards and Global Scientific Consensus

The field of genome editing is heavily regulated by scientific bodies and international human rights law frameworks. Prominent members of the scientific community have consistently echoed the need for a standardized structure towards the oversight of genome editing in humans.

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[15] ORGANIZING COMMITTEE OF THE THIRD INTERNATIONAL SUMMIT ON HUMAN GENOME EDITING, STATEMENT FROM THE ORGANIZING COMMITTEE OF THE THIRD INTERNATIONAL SUMMIT ON HUMAN GENOME EDITING, ROYAL SOC'Y (Mar. 8, 2023), https://royalsociety.org/news/2023/03/statement-third-international-summit-human-genome-editing/.

[16] Sandy Sufian & Rosemarie Garland-Thomson, *The Dark Side of CRISPR,* SCI. AM. (Feb. 16, 2021), https://www.scientificamerican.com/article/the-dark-side-of-crispr/.

[17] N Kubikova et al., *Deficiency of DNA Double-Strand Break Repair in Human Preimplantation Embryos Revealed by CRISPR-Cas9*, 38 HUM. REPROD. (2023), https://doi.org/10.1093/humrep/dead093.089.

[18] Michael Kosicki et. al., *Repair of CRISPR-Cas9–Induced Double-Stranded Breaks Leads to Large Deletions and Complex Rearrangements,* 36 NAT. BIOTECHNOL. 765 (2018).

[19] G. Owen Schaefer, *Why Treat Gene Editing Differently in Two Types of Human Cells?* THE CONVERSATION (Dec. 7, 2015), https://theconversation.com/why-treat-gene-editing-differently-in-two-types-of-human-cells-51843.

[20] Fergus Walsh, *Casgevy: UK Approves Gene-Editing Drug for Sickle Cell,* BBC (Nov. 16, 2023), https://www.bbc.com/news/health-67435266.

[21] Gina Kolata, *F.D.A. Approves Sickle Cell Treatments, Including One That Uses CRISPR,* N.Y. TIMES (Dec. 8, 2023), https://www.nytimes.com/2023/12/08/health/fda-sickle-cell-crispr.html.

[22]Adam Zamecnik, *CRISPR Gene Therapies: Is 2023 a Milestone Year in the Making?,* PHARM. TECH. (Jan. 3, 2023), https://www.pharmaceutical-technology.com/features/crispr-gene-therapies-is-2023-a-milestone-year-in-the-making/.

Rationales for international governance through uniform standards include prevention of medical tourism directed towards 'regulatory havens', protection of global human rights and medical ethics, common entitlement to and ownership of the human gene pool, and circumvention of unfair practices arising from genetic enhancement.[23] Harmonized standards also offer benefits like regulatory economies of scale, reduced administrative costs, shared responsibilities, and improved capacity through the exchange of best practices.[24] Therefore, understanding the global scientific consensus and internationally accepted rights-based frameworks addressing genomic research becomes paramount in determining the right approach to domestic regulation of revolutionary CRISPR-based technologies. The present section outlines the global regulatory landscape for genome editing technologies, explores prominent international standards along with notable critiques of prevailing ethical frameworks, and consolidates foundational consensus from key scientific literature; thereby setting crucial groundwork for subsequent discussions within the paper.

Advisory Bodies, International Instruments, and Overarching Principles

The Oviedo Convention is the only international legally binding instrument protecting human rights in the biomedical field.[25] It establishes standards for good medical practices, biomedical research, genetics, and transplantation of organs and tissues. Instruments such as the International Declaration on Human Genetic Data (2003), and the Nagoya Protocol (2010) govern genetics and biodiversity,[26] while the Nuremberg Code of 1947 and the Declaration of Helsinki (DoH) last amended in 2013 inform our understanding of ethical standards for research involving humans.[27] Similarly, the Universal Declaration on the Human Genome and Human Rights of 1997 and the Universal Declaration on Bioethics and Human Rights of 2005, guide bioethics and promote respect for human dignity, human rights, and fundamental freedoms.[28,29] International organizations in the field of biotechnology are often also aided by ethical committees such as the United Nations Educational, Scientific and Cultural Organization's

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[23] Gary Marchant, *Global Governance of Human Genome Editing: What Are the Rules?*, 22 ANNU. REV. GENOM. HUM. GENET. 385 (2021).

[24] NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, HUMAN GENOME EDITING: SCIENCE, ETHICS, AND GOVERNANCE (2017) [hereinafter NASEM Report].

[25] Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, *opened for signature* Apr. 4, 1997, 2137 U.N.T.S. 171 (entered into force Dec. 1, 1999) [hereinafter Oviedo Convention]

[26] Ananth Padmanabhan, et. al., *Modern Biotechnology and India's Governance Imperatives,* CARNEGIE ENDOWMENT FOR INTERNATIONAL PEACE, (Oct. 2, 2017), https://carnegie-production-assets.s3.amazonaws.com/static/files/CP_311_Padmanabhan_FNL4WEB.pdf.

[27] Michael Goodyear, Karmela Krleza-Jeric & Trudo Lemmens, *The Declaration of Helsinki*, 335 BMJ 624 (2007), https://doi.org/10.1136/bmj.39339.610000.BE.

[28] U.N. Educ., Sci., & Cultural Org. [UNESCO], Universal Declaration on the Human Genome and Human Rights, 29th Sess., Resolution 29C/16 (Nov. 11, 1997) [hereinafter UDHGHR].

[29] U.N. Educ., Sci., & Cultural Org. [UNESCO], Universal Declaration on Bioethics and Human Rights, General Conference of UNESCO, 33rd sess., Resolution 33 C/Res 36 (Oct. 19, 2005).

(UNESCO) International Bioethics Committee or the Council of Europe's Committee on Bioethics which act as policy advisors on issues arising out of technological developments.[30]

Non-binding legal instruments such as the Guidelines for Good Clinical Practice (GCP)[31] and the International Ethical Guidelines for Health-related Research Involving Humans (The Council for International Organizations of Medical Sciences (CIOMS) Guidelines)[32] are often touted as the standard ethical code for medical and clinical research. These guidelines aim to achieve two goals: implementing the principles of the DoH and adapting them specifically to the context of international biomedical research, particularly in low-resource settings.[33] However, even though the GCP lack the moral authority embodied by DoH and CIOMS guidelines, which focus primarily on ethical concerns, global regulatory frameworks have increasingly prioritized the former.[34] This has led to a growing disconnect between international ethical guidelines and domestic policies; a concerning trend as most global clinical trials are concentrated in lower and middle-income countries (LMICs) which are susceptible to such attenuated ethical codes.[35]

The CIOMS 2016 guidelines, though improved, face a lot of criticism for procedural flaws, including underrepresentation of the Global South in shaping guidance for LMICs and reliance on imperfect consensus methods.[36] Even the UNESCO declaration is disparaged by experts for its lack of specific authoritative guidance and the contention that many professional bioethicists choose to ignore and flout the recommendations.[37] This raises concerns about the diminishing relevance of non-statutory ethics frameworks in a globalized yet commercialized research context, and highlights the need for fairer and more inclusive processes.

It is important to note that the societal, scientific, and ethical debates highlighted by the International Commission on the Clinical Use of Human Germline Genome Editing in their 2020 consensus study[38] have also greatly informed the discourse surrounding human genome editing. However, while these debates promote academic dialogue about the overall safety of genomic interventions, they stop short of prescribing binding regulations for sovereign states, given the absence of a clear jurisdictional or authoritative mandate.

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[30] WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing, Human genome editing: a framework for governance (2021) [Hereinafter WHO Governance Framework].

[31] Int'l Council for Harmonisation of Tech. Requirements for Pharma. for Human Use [ICH], *Guideline on Good Clinical Practice (GCP)* (*approved* in 1996 through the adoption of E6 (R2) on Nov. 9, 2016).

[32] The Council for Int'l Orgs. of Med. Sci. (CIOMS), *International Ethical Guidelines for Health-related Research Involving Humans* (2016).

[33] Hans-Jöerg Ehni & Urban Wiesing, *Research Ethics for a Globalised World: The Revised CIOMS International Guidelines*, 2(3) Indian J Med Ethics 165, 165 (2017), https://ijme.in/wp-content/uploads/2017/03/253the165_research_ethics.pdf.

[34] Sunita Bandewar, *CIOMS 2016*, 2(3) Indian J Med Ethics 138, 138 (2017), https://doi.org/10.20529/IJME.2017.067.

[35] *Id.*

[36] *Id.*

[37] R Macklin, *Schuklenk's Critique of the CIOMS Guidelines: All Procedure, No Substance*, 2(3) Indian J Med Ethics 173-175 (2017), https://ijme.in/wp-content/uploads/2017/06/253the173_schuklenks_critique.pdf.

[38] Nat'l Acad. of Med., Nat'l Acad. of Sci. & Royal Soc'y, Heritable Human Genome Editing (2020) [hereinafter HHGE Report].

In consonance with the outcry for global accountability-and-oversight mechanisms, the World Health Organization (WHO) in 2018, came forward to establish the multidisciplinary Expert Advisory Committee on Human Genome Editing.[39] The Committee was expected to advise the Director General of the WHO in relation to national and global governance of human genome editing.[40] The WHO also launched the International Clinical Trials Registry Platform in 2020 to keep healthcare policymakers informed of genome editing clinical trials across the globe.[41] However, the WHO is not immune to scrutiny by ardent bioethicists, who believe that the organisation lacks procedural transparency.[42]

While several aspects crucial to the governance of human genome editing, such as international instruments, oversight mechanisms, and global ethical standards, have been preemptively put in place, however, a lack of binding jurisdiction and non-mandatory nature of these guidelines hinder the development of harmonized ethical standards for biomedical research and the ethical conduct of clinical trials worldwide.

International Moratorium

A moratorium, whether voluntarily complied with or enforceable by a state-sanctioned regulation, is a temporary prohibition of a contentious activity.[43] The Convention on Human Rights and Biomedicine **(**Oviedo Convention),[44] ratified by 29 countries, is a great example of international law enforcing a moratorium on the heritable germline editing of the human genome.[45] While Article 13 of the Convention restricts the modification of the human genome to preventive, diagnostic or therapeutic purposes and prohibits heritable genome edits, Article 18 forbids the creation of human embryos in pursuance of research. Noticeably, however, technologically advanced States like the UK, Germany, Sweden, Netherlands, Spain, Russia, Italy, Belgium, and Austria are not parties to this Convention.[46]

In contemporary times, Jennifer Doudna, and other celebrated scientists in the field of genome editing have called for an international moratorium on the use of heritable human genome editing, especially after the emergence of the novel CRISPR genome editing technology.[47] A time-bound moratorium is often preferred over an indefinite one to balance predictability and innovation.[48] Doudna, Eric Lander and Paul Berg are among many of the

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[39] WHO Expert Advisory Comm. on Dev. Glob. Standards for Governance & Oversight of Hum. Genome Editing, Report of the Second Meeting, (Aug. 26-28, 2019) https://www.who.int/publications/i/item/WHO-SCI-RFH-2019-02.
[40] HHGE Report, *supra* note 38.
[41] *International Clinical Trials Registry Platform (ICTRP)*, WHO, https://www.who.int/clinical-trials-registry-platform (last visited Jan. 13, 2024).
[42] Macklin, *supra* note 37.
[43] WHO Governance Framework, *supra* note 30.
[44] Oviedo Convention, *supra* note 25.
[45] Oviedo Convention, *supra* note 25, art. XIII.
[46] Rumiana Yotova, *Regulating Genome Editing Under International Human Rights Law*, 69(3) ICLQ 653, 669 (2020).
[47] Eric Lander et.al., *Adopt a Moratorium on Heritable Genome Editing*, 567 Nature 165 (2019).
[48] WHO Governance Framework, *supra* note 30.

influential figures who support such a temporary moratorium on the use of CRISPR in germline cells.

The International Summits on Human Genome Editing

Keeping in mind the rapid advancements in the field of genome editing, the National Academy of Sciences and the National Academy of Medicines of the United States launched the "Human Genome Editing Initiative" (HGEI) in 2015.[49] As an inaugural activity, the First International Summit on Human Gene Editing was organized in December 2015, in Washington, DC. The 'Second International Summit on Human Genome Editing' and the 'Third International Summit on Human Genome Editing' were organized in Hong Kong (2018) and London (2023), respectively.

These summits commonly concluded the following:

1. Clinical use of heritable human germline genome editing is strongly discouraged.
2. Intensive basic and preclinical research regarding the safety and risk-benefit analysis of human germline genome editing is of utmost importance.
3. Non-heritable somatic gene edits can be allowed under the existing domestic gene therapy regulations, subject to rigorous evaluation and safety requirements.
4. A responsible translational pathway outlining all the standards for preclinical evidence, professional ethics for clinical practitioners, and stakeholder involvement, *inter alia*, is quintessential.
5. With somatic therapeutic interventions becoming more commonplace, such treatments must be made equitable, affordable, and accessible to genetically diverse populations.
6. An inclusive global forum facilitating social, regulatory, and scientific debates on the safety, ethicality, and effectiveness of novel gene editing technologies is much needed.

These six key resolutions provide a clear view of the global scientific consensus on genome editing in humans, both heritable and otherwise.

The discussions herein thus help in understanding the consistent efforts undertaken by the international community in rallying behind responsible policy imperatives pertaining to CRISPR technology and similar innovations. We see a strong desire to prohibit germline editing until it is proven safe. The global scientific consensus supports rigorous pre-clinical research, inclusive collaborations with stakeholders, and making somatic gene therapies accessible.

A Comparative Analysis of Global Policies

Different national jurisdictions have had disparate approaches to the regulation of therapeutic interventions and clinical applications of human genome editing, including dedicated legislations, restrictive guidelines, and even a prohibitive rider on funding for genomic research corresponding to heritable changes. The present section adopts a comparative approach to

[49] *About | Human Genome Editing Initiative*, NAT'L ACAD. OF SCI., ENG'G. & MED., https://www.nationalacademies.org/our-work/human-gene-editing-initiative/about (last visited Jan. 23, 2024).

contextualize such diversity of domestic policies across the globe and find regulatory lessons for India within the complex web of policy frameworks that govern genome editing across borders.

Somatic gene therapy regulation remains largely unchanged, as non-heritable changes fit within existing frameworks. However, heritable genome editing rightly requires strict regulation to prevent unintended consequences for future generations. Instead of advocating for absolute harmonization of domestic laws all over the world, the authors find merit in having unique localized laws that meet internationally accepted standards.

A Snapshot of The Global Policy Landscape for Human Genome Editing

Barring a common inclination towards proscription of heritable genome editing in humans resulting in reproduction, the national responses to clinical applications as well as research using somatic and germline genome editing (not resulting in reproduction) have been diverse. This is mostly owing to the historical, cultural, economic, and social factors unique to these jurisdictions.[50] According to a comprehensive survey conducted by a Canadian bioethicist with others,[51] a considerable majority of the surveyed countries with relevant documents (75 of 96) explicitly prohibit heritable human genome editing resulting in reproduction, with just five of them allowing specific exceptions. Eleven countries, including the US, UK, and India, permit research in germline genome editing not leading to procreation.[52]

While heritable genome editing and embryonic gene edits remain ethically controversial, somatic cell treatments have found a greater acceptance. Due to the high precision of the CRISPR-Cas9 technology, somatic gene editing has been considered safer than traditional gene therapies and is, therefore, being governed through the pre-existing gene therapy regulation models for registration, standards for laboratory practices, clinical trials, and market approvals.[53]

Diversity of Legal Responses to Heritable Germline Genome Editing

Jurisdictions across the globe have sought to effectively ban the use of heritable human genome editing leading to reproduction, due in part to the He Jiankui fiasco coupled with the well-established scientific position that the risks and biosafety requirements concerning novel gene editing techniques are not entirely understood yet. A comparison between the biomedical policies of the US, UK, and the European Union (EU) reveals a stark difference in the methods used to regulate gene therapy products and research related to heritable genomic edits.

While the US does not have a specific federal statute banning heritable genomic editing in animals or humans,[54] a few states have laws governing research in human embryos.[55] In the absence of a federal legislation, the Federal Drug Administration (FDA) and National Institutes

[50] NASEM Report, *supra* note 24.
[51] Baylis, *supra* note 12.
[52] Baylis, *supra* note 12.
[53] Marchant, *supra* note 23.
[54] Kerry Lynn Macintosh, *The Regulation of Human Germline Genome Modification in the United States*, in HUMAN GERMLINE GENOME MODIFICATION AND THE RIGHT TO SCIENCE (Andrea Boggio et. al. eds., 2019).
[55] NASEM Report, *supra* note 24.

of Health (NIH) regulate clinical trials of germline editing in humans.[56] The NIH has maintained that it will not fund any uses of embryonic gene-editing in humans.[57] The US Congress has also imposed a de facto moratorium on heritable germline editing in humans through the "Dickey-Wicker" amendment which prohibits funding for projects that involve the creation of or risk of injury to human embryos.[58] Additionally, stringent safety and efficacy requirements are supposed to act as a regulatory deterrent.[59]

The UK, on the other hand, exercises a direct and centralized regulatory control in the form of the Human Fertilization and Embryology Act (HFEA) of 1990 which prohibits the insertion of genetically modified embryos into humans.[60] HFEA also regulates two germline interventions, namely mitochondrial donation and preimplantation genetic diagnosis (PGD).[61] The Medicines and Healthcare Products Regulatory Agency (MHRA) supervises the safe use of all medicinal products and medical devices in the UK[62] while the Gene Therapy Advisory Committee (GTAC) serves as the UK's national Research Ethics Committee (REC) for gene therapy clinical trials, as specified under the Medicines for Human Use (Clinical Trials) Regulations 2004.[63] The UK thus provides an alternative governance regime for gene therapies with a more specialized and vertically integrated regulatory infrastructure.[64]

As for the European Union, medicinal products for use by humans are regulated through Directive 2001/83/EC and Regulation 726/2004/EC, along with Regulation 1394/2007, also known as the Advanced Therapy Medicinal Products (ATMP) Regulation.[65] Other Commission Directives address investigational medicines, market authorizations, pharmacovigilance, and standards for clinical and commercial processes involving human tissues and cells.[66] Fundamental research is usually the domain of domestic regulation by member states, while clinical research is broadly harmonized by EU laws.[67]

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[56] Macintosh, *supra* note 54.
[57] NIH Director, *Statement on NIH Funding of Research Using Gene-Editing Technologies in Human Embryos*, NATIONAL INSTITUTES OF HEALTH, (Apr. 28, 2015), https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos (last visited Jan. 7, 2024).
[58] Joshua Seitz, *Striking a Balance: Policy Considerations for Human Germline Modification*, 16 SANTA CLARA J. INT'L L 60 (2018).
[59] Macintosh, *supra* note 54.
[60] The UK Parliament POST, *Human Germline Genome Editing*, (2020), (POSTNOTE Number 611), https://researchbriefings.files.parliament.uk/documents/POST-PN-0611/POST-PN-0611.pdf.
[61] Andy Greenfield, *Fearful Old World? A Commentary on the Second International Summit on Human Genome Editing*, 30(1-2) MAMM. GENOME 1(2019).
[62] Research & Enterprise Division, *Medicines and Healthcare Products Regulatory Agency (MHRA) Review*, UNI. OF BRISTOL, https://www.bristol.ac.uk/red/research-governance/ethics/mhra-review/ (last visited Jan. 12, 2024).
[63] NHS Health Research Authority, *Gene Therapy*, NHS, https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/gene-therapy/ (last updated Feb. 26, 2020).
[64] NASEM Report, *supra* note 24.
[65] Carolina Iglesias-Lopez et. al., *Regulatory Framework for Advanced Therapy Medicinal Products in Europe and United States*, 10 FRONT. PHARMACOL. 921(2019), https://doi.org/10.3389/fphar.2019.00921.
[66] *Legal framework: Advanced therapies*, EUR. MED. AGENCY, https://www.ema.europa.eu/en/human-regulatory-overview/advanced-therapy-medicinal-products-overview/legal-framework-advanced-therapies (last visited January 12, 2024).
[67] Aurélie Mahalatchimy & Emmanuelle Rial-Sebbag, *Deciphering the Fragmentation of the Human Genome*

Diversity in legal responses to genomic editing in humans is also reflected in the divergent legal devices deployed by various nations to prohibit germline genome editing in humans explicitly or effectively. Certain nations use criminal laws to regulate heritable germline genome editing. For instance, Canada outrightly criminalizes heritable genomic alterations in humans and embryos through the Assisted Human Reproduction Act,[68] while China utilizes its criminal law to punish "illegal medical practices" as seen in the case of He Jiankui's prosecution.[69] Additionally, China also has new civil penalties for violations of ethical norms surrounding gene editing.[70] In India, as also seen in Japan, Ireland, Turkey, and Egypt, biomedical practices related to human genome editing are governed by restrictive guidelines.[71] However, these restrictive guidelines, are less enforceable than legislations.[72] On the other hand, countries like Chile, Colombia, Mexico, and Panama absolutely prohibit even somatic genome editing due to concerns that it could be used for enhancement purposes.[73]

The above overview thus highlights that the regulation of genome editing, heritable and otherwise, varies across jurisdictions, shaped by distinct socio-economic and cultural realities. Most countries strive to balance adherence to international ethical standards with fostering scientific innovation, while prioritizing the protection of their vulnerable populations from possible intergenerational risks.

Regulatory Lessons for India

Despite the proactive biomedical policies, India can draw valuable regulatory lessons from frameworks worldwide. It may be argued that the UK's centralized and patient-centric regulations offer key takeaways not just for India but for most developing countries. For example, MHRA has admirably accounted for the experiences of clinical participants of the Casgevy (the world's first licensed CRISPR therapy) trials while granting licensing approvals.[74] After conducting a preliminary assessment of the risks, benefits and data, the MHRA gave due consideration to patient contribution and stakeholder involvement, which has gone on to serve as a valuable lesson for Indian lawmakers.

India can also learn from the UK's emphasis on vulnerability in clinical research, recognizing that participants may not always appear overtly vulnerable but could still face coercion or undue pressure. The UK regulations stress the importance of understanding

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Editing Regulatory Landscape, 3 (793134) FRONT. POLIT. SCI. 1 (2022), https://doi.org/10.3389/fpos.2021.793134.

[68] Erika Kleiderman & Ian Norris Kellner Stedman, *Human Germline Genome Editing is Illegal in Canada, But Could it be Desirable for Some Members of the Rare Disease Community?*, 11 J. COMMUNITY GENET.129 (2020).

[69] Shuang Liu, *Legal Reflections on the Case of Genome-Edited Babies*, 5 GHRP 24 (2020).

[70] Dennis Normile, *In Wake of Gene-Edited Baby Scandal, China Sets New Ethics Rules for Human Studies,* SCIENCE (Mar. 7, 2023), https://www.science.org/content/article/wake-gene-edited-baby-scandal-china-sets-new-ethics-rules-human-studies.

[71] WHO Governance Framework, *supra* note 30.

[72] Liu, *supra* note 69.

[73] HHGE Report, *supra* note 38.

[74] Medicines & Healthcare products Regulatory Agency, *The Importance of Giving Patients a Voice in the Approval of New Sickle Cell Treatment*, GOV.UK (Nov. 6, 2024), https://www.gov.uk/government/case-studies/the-importance-of-giving-patients-a-voice-in-the-approval-of-new-sickle-cell-treatment (last visited Nov. 14, 2024).

vulnerability on a case-by-case basis, ensuring informed consent is properly obtained without passive assent, especially for marginalized groups.[75] By adopting a similar framework, India could better protect participants' rights and improve ethical oversight in clinical trials, ensuring that vulnerable populations are not exploited or overlooked.

India's Regulatory Landscape for Biomedicine and Genome Editing

With a biotechnology industry estimated to be valued at USD 150 billion by the fiscal year 2025, India is ranked amongst the top 12 biotech destinations in the world.[76] Unsurprisingly, the Indian regulatory apparatus is no stranger to the governance of modern biotechnological innovations such as recombinant DNA technology, transgenic genetic engineering, and the more recent precision genome editing techniques. This section involves a study of the existing biotechnology laws in India and identifies the ones relevant to the governance of CRISPR technology.

Among the oldest medical research organizations globally, the Indian Council of Medical Research (ICMR) serves as the apex body for formulating, coordinating, and promoting biomedical research in India.[77] The ICMR, in collaboration with the Department of Biotechnology (DBT), released the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants in 2017[78] and the National Guidelines for Gene Therapy Product Development and Clinical Trials in 2019[79] to govern the ethical aspects of clinical as well as academic research involving human participants and product development using genome editing, respectively. The 2017 Ethical Guidelines create overarching general principles that cover several aspects crucial to safe and ethical biomedical research, such as responsible conduct of research (RCR), ethical review mechanisms, informed consent procedures, protection of vulnerable groups, clinical trials, public health research doctrine, procedures for human genetics testing and the storing of biological materials and biobanking, etc. More importantly, the guidelines put in place the much-necessary interim ban on the use of heritable germline gene editing in humans.

These guidelines complement India's main drug control legislation, the Drugs and Cosmetics Act of 1940, implemented by its apex drug controller, the Central Drugs Standard Control Organization (CDSCO).[80] The CDSCO was established under the aegis of the

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[75] UK Research and Innovation, *Research with Potentially Vulnerable People*, UKRI, (2023) https://www.ukri.org/councils/esrc/guidance-for-applicants/research-ethics-guidance/research-with-potentially-vulnerable-people/ (last visited Nov. 14, 2024).

[76] Department of Biotechnology (Govt. of India), *National Biotechnology Development Strategy [2021-2025]*, (2021), https://dbtindia.gov.in/sites/default/files/National%20Biotechnology%20Development%20Strategy%202021-25.pdf.

[77] *About Us*, ICMR, https://main.icmr.nic.in/content/about-us, (last visited Jan. 17, 2024).

[78] Indian Council of Medical Research, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, (Issued in October, 2017).

[79] Indian Council of Medical Research, National Guidelines for Gene Therapy Product Development and Clinical Trials, (Issued in 2019) [hereinafter GTP Guidelines].

[80] Nishith Desai Associates, *Clinical Trials and Biomedical Research in India — Legal and Regulatory Framework*,

Directorate General of Health Services and the corresponding Ministry of Health & Family Welfare,[81] and is responsible for the formal approval of drugs, regulation and registration of clinical trials, the establishment of standards for drugs, oversight of the quality of imported drugs in India, and coordination with the State Drug Control Organizations.[82] The New Drugs and Clinical Trials Rules of 2019 (hereinafter, the NDCT Rules) read with the Good Clinical Practices (GCP) formulated by the CDSCO and the ICMR Guidelines for Biomedical and Health Research Involving Human Participants, 2017 outline the formal laws about clinical trials and clinical research in India, respectively.[83] The National Guidelines for Gene Therapy Product Development and Clinical Trials of 2019 define a gene therapy product (GTP) as *"any entity which includes a nucleic acid component being delivered by various means for therapeutic benefit,"* and clearly state that genetic modifications resulting from the use of CRISPR and other similar technologies, including stem cells corrected for mutations, would be considered as "GTP."[84] As per the NDCT Rules, the GTPs fall under the 'new drug' category and shall always be deemed to be 'new drug'. Read conjointly, this makes CRISPR a direct subject of regulation for both the GTP Guidelines as well as the NDCT Rules.

Apart from these foundational rules and guidelines, research in genome editing is also regulated by the National Guidelines for Stem Cell Research, 2017[85] and the National Ethical Guidelines for Biomedical Research Involving Children, 2017.[86] Due to the former, genome modification (including CRISPR-based interventions) of stem cells, germ-line stem cells, gametes and human embryos are strictly restricted to in vitro studies and the use of stem cells in patients in the absence of an approved clinical trial is considered unethical and illegal. The latter govern the ethical and legal issues arising out of biomedical research in neonates and children and mandates periodic re-consent for identifiable biological samples stored by children during genetic research, once they attain the age of assent or consent.

Additionally, Ethics Committees also regulate the research and trials in relation to CRISPR in India. The NDCT Rules specify requirements for the two types of Ethics Committees (ECs) in India, i.e., the ECs for clinical trials, bioavailability, and bioequivalence studies, as well as the ECs for biomedical and health research.[87] In accordance with these rules, a National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), has also been set up within the Department of Health Research (DHR) to process applications by the ECs seeking

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NISHITHDESAI.COM, (2023), https://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research_Papers/Clinical-Trials-in-India.pdf (last updated Feb., 2025).

[81] *About CDSCO*, CDSCO, https://cdsco.gov.in/opencms/opencms/en/Home/#:~:text=The%20Central%20Drugs%20Standard%20Control,Authority%20(NRA)%20of%20India, (last visited Jan. 18, 2024).

[82] *Id*.

[83] Nishith Desai Associates, *supra* note 80.

[84] GTP Guidelines, *supra* note 79, at 5.

[85] Indian Council of Medical Research, National Guidelines for Stem Cell Research, (Issued in October 2017).

[86] Indian Council of Medical Research, National Ethical Guidelines for Biomedical Research Involving Children, (Issued in October 2017).

[87] Neelu Singh et.al., *New drugs and clinical trials rules 2019: Changes in responsibilities of the ethics committee*, 11(1) PERSPECT. CLIN. RES. 37 (2020).

mandatory registration to conduct biomedical and health research involving human participants.[88] However, a majority of the existing ECs are yet to be registered with the NECRBHR, predominantly due to a lack of awareness regarding the NDCT Rules.[89]

More specifically though, CRISPR-based therapeutic innovations are likely to be scrutinized by Subject Expert Committees (SECs), which assist the CDSCO in evaluating applications across different areas of investigational biomedicine.[90] SECs make advisory recommendations on applications, ranging from marketing authorizations to reviews of Phase IV clinical trials, with the CDSCO making the final decisions. [91] Hence, Indian lawmakers need to proactively redefine the regulatory ambit and procedural routes for SECs in the context of CRISPR gene therapies.

Overall Efficacy of the CRISPR-Specific Laws in India

A crucial role in the governance of CRISPR-mediated gene therapies is likely to be played by the central drug regulation body, the CDSCO, through the evaluation of applications for clinical trials and protocols, post-marketing surveillance, and accelerated approvals under the NDCT Rules of 2019. Clinical trial protocols and regulations in India have come a long way in improving the status of effective implementation and provision of safeguards against non-compliance.

Schedule Y, as amended in 2005, read with the Guidelines on Good Clinical Practice in India, 2001 (CDSCO-GCP) formed the basis of a pro-industry four-phase clinical trial mechanism.[92] However, factors such as deficient ethical review and lack of provisions for compensation lead to exploitation, and in some grave cases, deaths of the clinical trial participants.[93] To remedy the same, new rules were introduced in the Drugs and Cosmetics Rules of 1945.[94,95,96] These cover free medical management, financial compensation in case of injury or death of clinical trial participants, prerequisites for grant of permissions to conduct clinical trials and mandatory registration of Ethics Committees. Later, the case of *Kalpana Mehta v. Union of India*[97] that shed light on the persistent child abuse and rampant human rights violations faced by vulnerable communities during clinical trials, finally paved the way for the incumbent New Drugs and Clinical Trial Rules, 2019.[98] Under the new CT Rules, sponsors of clinical trials

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[88] Balu Venugopal et.al., *Overview of the National Ethics Committee Registry for Biomedical and Health Research in India: Stepping Up to Safeguard the Ethical Aspect of Research Involving Human Participants*, 55(4) INDIAN J. PHARMACOL. 251, 252 (2023).
[89] *Id*. at 255.
[90] Blog Morulaa, *SEC - Special Expert Committee, India Update,* MORULAA HEALTHTECH PVT. LTD., (Apr. 17, 2024) https://morulaa.com/blog-morulaa/sec-special-expert-committee/ (last visited Jan. 23, 2024).
[91] *Id*.
[92] Nishith Desai Associates, *supra* note 80.
[93] *Id.*
[94] Govt. of India, Ministry of Health and Family Welfare, G.S.R. 53(E) (Notified on January 30, 2013).
[95] Govt. of India, Ministry of Health and Family Welfare, G.S.R. 63(E) (Notified on February 1, 2013).
[96] Govt. of India, Ministry of Health and Family Welfare, G.S.R. 72(E) (Notified on February 8, 2013).
[97] Kalpana Mehta v Union of India, (2018) 7 SCC 1 (India).
[98] Nidhisha Garg, *Understanding the Regulatory Regime for Clinical Trials in India*, LIVELAW (Aug. 21, 2020)

are liable to pay compensation and the trial subjects are entitled to receive such financial compensation and medical assistance in case of death, permanent disability, or any other injury.[99] Throughout the clinical trials, the investigators are required to adhere to three cardinal principles of clinical trials, namely justice, respect for persons, and beneficence, as set out in the Helsinki Declaration of 1964.[100] Moreover, the sponsors are made responsible for ensuring that the production of a new drug or investigational new drug (IND), whether imported or domestically manufactured, adheres to Good Manufacturing Practices (GMPs) outlined in Schedule M of the Drugs and Cosmetic Rules 1945.[101]

The GTP guidelines also ensure a multi-level approval process for the development of gene therapies in projects receiving financial support and this includes compulsory approvals from authorities like the Gene Therapy Advisory and Evaluation Committee (GTAEC) and CDSCO, as well as approvals by Institutional Biosafety Committees (IBSC) and the Review Committee on Genetic Manipulation (RCGM) wherever the GTPs require preclinical animal studies.[102] Additionally, the Chemistry, Manufacturing and Control (CMC) requirements also guide the development, manufacturing and subsequent testing of new GTPs.[103] Importantly enough, there is also a provision towards a priori arrangement for post-trial access and benefit-sharing after completion of research to ensure that the benefits are translated to meaningful outcomes for the participants or communities and not just restricted to academic contribution.[104] While these guidelines by themselves make for comprehensive regulation of CRISPR-mediated therapies, the reality of implementation of such guidelines may manifest differently. The GTAEC, an expert committee, has been ostensibly established by the Department of Health Research (DHR), Ministry of Health and Family Welfare of the Government of India.[105] An independent body of experts, the GTAEC is tasked with supporting investigators and industry stakeholders and offering pre-Investigational New Drug (IND) consultations.[106] However, there is very little publicly available information regarding the current state, composition and workings of the GTAEC, compounded by the fact that the official website for this independent body is non-operational.

Keeping in mind the fragmented regulatory landscape that governs the modern biotechnologies in India, it is suggested that focused legislation for newer groundbreaking biotechnology applications such as CRISPR technology be introduced. In governing CRISPR, the legislators must consider enforceable laws for transparency in biomedical research,

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https://www.livelaw.in/columns/understanding-the-regulatory-regime-for-clinical-trials-in-india-161763.

[99] Nishith Desai Associates, *supra* note 80.

[100] Garg, *supra* note 98.

[101] *Id.*

[102] GTP Guidelines, *supra* note 79.

[103] *Id.*

[104] Roli Mathur & Soumya Swaminathan, *National ethical guidelines for biomedical & health research involving human participants, 2017: A commentary,* 48(3) INDIAN J. MED. RES. 279 (2018).

[105] S.P. Singh Baghel (Minister's answer to the Lok Sabha Unstarred Question No. 304), *Tackling Sickle Cell Anemia Using Crisp Cas-9 Therapy*, THE MINISTRY OF HEALTH AND FAMILY WELFARE, (Jul. 21, 2023), https://sansad.in/getFile/loksabhaquestions/annex/1712/AU304.pdf?source=pqals (last visited Jan. 24, 2024).

[106] *Id.*

mandatory publication of accurate clinical trial data, grievance redressal mechanisms in the form of independent statutory bodies, and criminal penalties for severe human rights violations or brazenly unethical experiments. Much of India's existing regulatory framework consists of restrictive guidelines lacking definitive and deterrent penalties, which are dispersed across numerous regulatory authorities, handbooks, and guidelines. Consolidating these rules into a unified central legislation would simplify the regulation of genome technologies, establish accountability mechanisms, and introduce enforceable penalty provisions for severe biosafety violations – an essential step for a diverse and vulnerable population like India's.

The authors firmly believe that India needs a strong legislative framework to regulate the use of CRISPR therapies in humans which effectively balances innovation, patient safety, and ethical considerations. Targeted legislation addressing niche governance needs and specific subjects of regulation is not uncommon in Indian policymaking. Thus, the enactment of a central statute that pioneers the regulation of genome editing techniques, particularly in relation to CRISPR therapies for humans, would not only set a crucial precedent for future technological advancements with high stakes but also unequivocally establish India's approach to key bioethical challenges. Drawing from the Biotechnology Regulatory Authority of India (BRAI) Bill, 2013, the legislation should focus on mandatory enforceable provisions in a unified regulatory approach. Some of the key features of the proposed legislation could include:

(a) establishment of a *National Gene Therapy Regulatory Authority (NGTRA)* having expertise in overseeing the regulation of research, trials, and clinical applications of gene therapies;
(b) consolidating fragmented guidelines into a centralized regulatory framework;
(c) enforcement of clear and legally binding penalties for willful non-compliance (such as unsafe applications);
(d) integration with the newly enacted Digital Personal Data Protection Act, 2023 to protect genetic information; and
(e) regular public consultations.

Another crucial consideration while legislating on the matter is the necessitation of post-trial obligations, including continued responsibility upon sponsors to prove the safety and efficacy of the drug, post-marketing surveillance reports, periodic safety updates to the regulators, and lastly, compassionate access to the study drug for trial participants in the absence of alternate remedy.[107] The SECs play a decisive role in defining the national roadmap for research in new drugs, criteria for marketing approvals and evaluation of non-clinical data as well as clinical trial data (phases I-IV) for new drugs.[108] Therefore, it is equally important to incorporate procedural and structural changes that involve transparent decision-making and dedicated gene-editing experts in existing SECs, respectively.

While high-income countries such as the United States can resolve to forego federal legislation on the matter, such an option seems unfeasible for India due to the severe healthcare

[107] Nishith Desai Associates, *supra* note 80.
[108] Drug Controller General (India), Panels of experts for Subject Expert Committees, Order in F. No. 12-01/14-DC(Pt.20), (Issued on January 5, 2015).

and socio-economic inequalities prevalent in the country. For life-threatening genetic disorders like the sickle-cell disease, where primary care in the form of the drug hydroxyurea or blood transfusions is not widely available,[109] expecting tertiary healthcare through equitable distribution of CRISPR-mediated gene therapies could feel like a distant dream for many. Therefore, the authors opine that strengthening public health infrastructure, sufficient oversight through responsible legislation, well-functioning regulatory authorities, and finally an informed precautionary approach should take precedence over a blind race for technological advancements.

Governance of CRISPR in Light of Amendments to Existing Indian Laws

In addition to the main biotechnology regulatory framework, other ancillary regulations have the potential to highly influence manufacturing, marketing, licensure and approval processes for CRISPR-based gene therapy products. Through this section, the authors predict the impact of newly amended Indian laws, namely the NDCT (Third Amendment) Rules, 2022 and the Patents (Amendment) Rules, 2024 on the regulation of CRISPR therapies in India.

The NDCT (Third Amendment) Rules, 2022 were introduced to further modify the NDCT Rules of 2019, resulting in the present amendment.[110] An important feature of these newly amended NDCT rules is the concept of "deemed approval". For example, in the absence of a formal communication by the Central Licensing Authority of CDSCO ("CLA" hereinafter) in the specified forty-five working day period, registration of an Ethics Committee shall be deemed to be granted and considered legally valid for all purposes.[111] Similarly, where the CLA has provided no communication in ninety working days, legally valid permission to conduct clinical trials shall be deemed to have been granted.[112] Rule 53(1) provides for similar deemed approvals to manufacture new drugs such as CRISPR-based GTPs or investigational new drugs for clinical trials, bioavailability or bioequivalence study, or tests and analyses.

While such amendments might nudge the CLA to make timely decisions, they could also result in abuse of said provisions and lead to deemed approvals of clinical trials and studies without thoroughly processed prior approvals by the Licensing Authority.

In fact, CRISPR GTPs can become crucial in treating life-threatening or rare diseases like sickle cell disease which holds special relevance to India,[113] and thus qualify for the "accelerated approval process" as set out in the new NDCT Rules of 2019. After a life-saving new drug secures accelerated approval, the CLA may consider granting marketing approval based on just the clinical trial data in Phase-II, provided remarkable efficacy with a defined dosage has been

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[109] Sarojini Nadimpally et. al., *How Subpar Treatment Options Allow Sickle Cell Disease to Persist | Explained*, THE HINDU (Mar. 27, 2024), https://www.thehindu.com/sci-tech/science/sickle-cell-disease-crispr-hydroxyurea-healthcare-amenities/article67994033.ece.

[110] Govt. of India, Ministry of Health and Family Welfare, G.S.R 778(E) (Notified on October 14, 2022).

[111] The New Drugs and Clinical Trials (Third Amendment) Rules, 2022, Rule 8 (3) (ii).

[112] *Id.* at rule 24.

[113] Sangeeta Chattoo et.al., *A Social Profile of Deaths Related to Sickle Cell Disease in India: A Case for an Ethical Policy Response*, 11 FRONT. PUBLIC HEALTH, 1 (2023).

proved in those trials.[114] This provision clubbed with the "deemed approval" feature granted by the recent NDCT Rules of 2022, gives us a new class of approvals i.e., "deemed accelerated approvals" for serious medical conditions and diseases. And although CDSCO can review clinical trials having automatic approvals under the form CT-4A, the legal sanctions that the CLA is empowered to impose are restricted to milder forms of penalties such as issued warnings, rejection of clinical trial results, suspension or cancellation of the permission granted, and disqualification of the investigator or the sponsor from conducting any future clinical trials for a period as decided by the CLA. These, in the opinion of the authors, do not act as sufficient regulatory deterrents.

Even in the United States, a drug with accelerated approval needs to undergo Phase III studies to evaluate the benefit-risk ratio.[115] Therefore, deemed approvals for gene therapies with just the Phase-II clinical trial data to their merit could set a dangerous precedent in India. Additionally, the newly notified Patents (Amendment) Rules, 2024, while being innovator-friendly, also create certain opportunities for misuse. The introduction of fees for pre-grant opposition filings could hamper the ability of patient groups to initiate a pre-grant opposition, a crucial exercise towards ensuring the accessibility of therapeutic interventions.[116] Moreover, extension of the timeframe for submitting work statements regarding manufacturing particulars, and discretionary powers to patent controllers regarding who can file pre-grant oppositions, makes room for personal bias and misuse of the patent laws by pharmaceutical lobbies.

An Exploration of the Bioethical and Socio-Political Considerations

Heritable germline editing in humans has been a controversial subject for several ethical, scientific, legal, sociopolitical, and theological reasons. In this section, the authors investigate some of the universal bioethical concerns that demand the attention of policymakers of genome editing regulations. Furthermore, we delve into bioethical considerations that are especially significant for the governance of human genome editing in India.

Universal Ethical Concerns in Policymaking for Genome Editing

Popular narratives label germline modifications as an existential threat to humanity as a species and a potential tool for eugenic experiments.[117] The multigenerational impacts of heritable germline editing also raise questions surrounding informed consent, given that future generations will have to ultimately face the consequences of genetic procedures they did not

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[114] The New Drugs and Clinical Trials Rules, 2019.

[115] Dinesh Thakur, *How legit are Emergency Use Authorizations in India?*, DINESH THAKUR (Jul. 26, 2020), https://dineshthakur.com/2020/07/26/how-legit-are-emergency-use-authorizations-in-india/ (last visited Jan. 23, 2024).

[116] T C James, *Zoomed Out| Pharma Patents —Why India's IPR Regime Surrendering To Global Pressure*, CNBC TV 18 (Oct. 30, 2023), https://www.cnbctv18.com/healthcare/access-to-cheaper-medicines-under-threat-changing-pharma-patent-law-why-indias-ipr-regime-surrendering-to-global-pressure-18184011.htm.

[117] ANA NORDBERG, PANEL FOR THE FUTURE OF SCIENCE AND TECHNOLOGY (STOA), EUROPEAN PARLIAMENT, GENOME EDITING IN HUMANS: A SURVEY OF LAW, REGULATION AND GOVERNANCE PRINCIPLES, (2022) https://www.europarl.europa.eu/stoa/en/document/EPRS_STU(2022)729506.

consent to.[118] And despite all the counterarguments, the concern that prenatal screening and genome editing to eliminate certain genetic disabilities could devalue people with these conditions, remains relevant in the ethical debate on heritable genome editing.[119] Additionally, reservations about heritable edits also come from religious and philosophical factions. For example, the Islamic faith is accepting of somatic gene editing but objects to heritable changes in the human genome due to the belief that such applications overreach human authority in the universe.[120] The Japanese consider human embryos "sprouts of human life" deserving of protection[121] while the Catholics believe in the primacy of all human life which they argue begins at conception such that each human embryo is distinct and comparable to a whole human being.[122] These religious groups shape individual morality and in turn, influence the policies through their electoral power.[123]

The use of human germline editing could also blur the distinction between diversity and disability[124] as well as between therapy and enhancement.[125] The scientists at the First International Summit on Human Genome Editing insightfully talk about how the long-term harms of germline editing could outweigh the benefits due to the unpredictable nature of such genetic interventions.[126] They also worry about the technology being capable of reinforcing and exacerbating prevalent social hierarchies based on racial or ethnic divides.[127] In light of these serious concerns, meticulous scrutiny of heritable human genome editing through the lens of bioethics becomes essential.

The preservation of the human gene pool and human rights from the unethical or immoral applications of biotechnology has been a recurrent theme globally, partly owing to the popularity of the eugenics movement in the early 20th century. For example, the Universal Declaration on the Human Genome and Human Rights[128] enshrines the ideals of an inherent right to dignity and non-discrimination based on genetics,[129] respect for human rights and fundamental freedoms,[130,131] equitable access to the benefits arising from advances in biology, genetics and medicine,[132] and the establishment of independent, multidisciplinary and pluralist ethics

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[118] Marchant, *supra* note 23.
[119] Bjørn Hofmann, *'You are inferior!' Revisiting the expressivist argument*, 31(7) Bioethics 505 (2017).
[120] 4 National Academies of Sciences, Engineering, and Medicine, Second International Summit on Human Genome Editing: Continuing the Global Discussion: Proceedings of a Workshop–in Brief (2019).
[121] *Id.*
[122] James Delaney, *The Catholic Position on Germ Line Genetic Engineering*, 9 AJOB 33 (2009). *See also*, Kevin FitzGerald, *Human Genome Editing, A Catholic Perspective*,17(1) NCBQ 107 (2017).
[123] NASEM Report, *supra* note 24.
[124] National Academies of Sciences, Engineering, and Medicine, International Summit on Human Gene Editing: A Global Discussion (2015) [hereinafter First International Summit].
[125] Henry Greely, *CRISPR'd babies: human germline genome editing in the 'He Jiankui affair'*, 6(1) JLB 111 (2019), https://doi.org/10.1093/jlb/lsz010.
[126] First International Summit, *supra* note 124.
[127] *Id.*
[128] UDHGHR, *supra* note 28.
[129] *Id.*, art. II.
[130] *Id.*, art. X.
[131] *Id.*, art. XV.
[132] *Id.*, art. XII.

committees[133] to address the social, ethical, and legal consequences of applications and research on the human genome. Accordingly, upholding medical ethics as a quintessential part of the rule of law is crucial to protecting the rights of vulnerable and marginalized populations in our deeply unequal societies.[134]

One also finds increasing outcry from the global scientific community to hold off on the usage of heritable germline editing in research and clinical applications. This self-censorship model adopted by the scientists, together with the regulatory prohibitions on genetic interventions leading to reproduction, has effectively hindered the threat of commercialization of human germline editing so far. While sociocultural differences across jurisdictions might eventually lead to different domestic laws for applications of genome editing, having common overarching principles to inform our regulatory policies will go a long way in the harmonization of biomedical policies globally.[135]

In addition to professional self-regulation and government regulation, the existing ethics systems can also play an important role in the governance of human genome editing.[136] This includes operational standards, review committees and research ethics guidelines.[137] These ethics systems can also significantly benefit from community investment and public engagement.[138] Innovative payment models (such as installments), along with mobilization of public awareness can be prioritized to address the concerns surrounding equitable access to inherently expensive gene therapies within and across domestic jurisdictions, especially the low and middle-income countries (LMICs).[139]

The future of heritable genome editing in humans, thus, cannot be determined in the absence of a comprehensive global debate on the bioethical as well as the socio-political ramifications and multifaceted stakeholder inclusion. After all, one cannot disagree much with the wise approach of practicing prudence over prometheanism.[140]

Bioethical Considerations Crucial for Lawmaking in India

India is best described as a land of stark differences. This is aptly exemplified by the fact that although India is currently the fifth largest economy, it is still categorized as a lower-middle-income country as per the World Bank's classification.[141] Similarly, while India is internationally

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[133] *Id.*, art. XVI.
[134] Dinesh Thakur, *Nationalism has no place in drug regulation*, DINESH THAKUR (Jan. 29, 2021), https://dineshthakur.com/2021/01/29/nationalism-has-no-place-in-drug-regulation/.
[135] NASEM Report, *supra* note 24.
[136] WHO Governance Framework, *supra* note 30.
[137] *Id.*
[138] *Id.*
[139] Kenneth Cornetta et.al., *Gene therapy access: Global challenges, opportunities, and views from Brazil, South Africa, and India,* 30(6) MOL. THER. 2122 (2022).
[140] Ted Peters, CRISPR, the Precautionary Principle, and Bioethics, 13(3) THEO. & SCI. 267 (2015).
[141] Gyanendra Keshari, *India may become upper-middle income country by FY31: S&P*, DECCAN HERALD (Sept. 20, 2024), https://www.deccanherald.com/india/india-may-become-upper-middle-income-country-by-fy31-s-p-3198187.

recognized as a leading hub for medical tourism, its poorest states still experience infant mortality rates that surpass those in sub-Saharan Africa.[142]

Notwithstanding a Pew Research Centre report[143] that suggests that most adults in India across religious lines view gene-editing research more favourably than their counterparts in other nations, it is highly likely that the opinions of impoverished or illiterate individuals were not considered in these surveys, potentially distorting the true consensus of the Indian public. A significant portion of India's disenfranchised populations, already divided on the lines of caste, class, gender, ideologies, et cetera, stand to be critically impacted by any changes in ethical frameworks governing biomedical research and clinical trial policies. Therefore, these policies must prioritize social justice, civil participation, and risk mitigation to protect their interests. Meanwhile, gene-editing therapies are, at least initially, likely to remain limited to wealthy nations with advanced healthcare systems. A geneticist at University College London (UCL) notes that these treatments require complex technology to modify stem cells, making them impractical for high-volume production or administration in LMICs.[144] In India, where healthcare access is acutely unequal, this could exacerbate existing disparities, with advanced treatments becoming attainable only to affluent consumers.

Another major concern for Indian lawmakers is "Ethics Dumping". This phenomenon occurs when research participants or resources in LMICs are deliberately exploited, either because such research is prohibited in high-income countries or due to a lack of ethical awareness among researchers or weak research governance in the host country.[145] The clinical trials conducted in India from 1998 to 2015 on cervical cancer screening exemplify this unethical practice, wherein trials violated informed consent procedures and participants' rights to life and health, misrepresenting the standard of care and exploiting vulnerable populations.[146] Approximately 141,000 women were denied standard-of-care pap smear testing, placing them at a known risk of invasive cervical cancer, leading to a shocking number of 254 deaths in the no-screening arm.[147] Essential ethical standards were ignored even by international sponsors such as the NIH, highlighting the need for universal adherence to ethical research principles and robust accountability systems. The trials thus reflected a failure to balance research needs with participant rights, underscoring inequities in global research ethics enforcement.

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[142] Oxfam, *India: Extreme Inequality in Numbers*, OXFAM INT'L, https://www.oxfam.org/en/india-extreme-inequality-numbers (last visited Nov. 18, 2024).
[143] Pew Research Center, *Biotechnology Research Viewed with Caution Globally, but Most Support Gene Editing for Babies to Treat Disease*, PEW RESEARCH CENTER, (Dec. 10, 2020), https://www.pewresearch.org/science/2020/12/10/biotechnology-research-viewed-with-caution-globally-but-most-support-gene-editing-for-babies-to-treat-disease/.
[144] Carissa Wong, *U.K. Becomes First Country to Approve a CRISPR Disease Treatment*, SCI. AM. (Nov. 16, 2023), https://www.scientificamerican.com/article/u-k-becomes-first-country-to-approve-a-crispr-disease-treatment/.
[145] Doris Schroeder et.al., *Chapter 1 Ethics Dumping: Introduction*, in SPRINGER BRIEFS IN RESEARCH AND INNOVATION GOVERNANCE (Doris Schroeder et.al. eds., 2018).
[146] Sandhya Srinivasan et.al., *Chapter 5 Cervical Cancer Screening in India*, in SPRINGER BRIEFS IN RESEARCH AND INNOVATION GOVERNANCE (Doris Schroeder et.al. eds., 2018).
[147] *Id.*

In India, where the "Right to Health" has been read into Article 21 of the Indian Constitution as an inseparable part of the fundamental "Right to Life & Personal Liberty" via judicial interpretation, bioethical protection of vulnerable groups and necessitating critical healthcare for all is not only imperative but a legal mandate for the Indian State.

Stakeholder Involvement and the Power of Public Perception

Several authoritative reviews of the ethical acceptability of human germline genome editing underscore the value of comprehensive public debate and stakeholder engagement as a prerequisite to formulating any definitive rules or legislation for gene editing.[148] Public and stakeholder engagement is especially important in regulating controversial sciences wherein moral and religious beliefs are involved, which also holds true for heritable germline gene editing.[149] As such, nation-states around the world face the challenge of understanding the particular and diverse needs of their respective societies and formulating inclusive policies for the governance of CRISPR technology accordingly.

Importance of Public Participation and Stakeholder Engagement

Bioethical considerations in policymaking, along with a focus on multicultural civil society, democratic values, and equitable distribution of risks and benefits, are just as important as clinical evaluations of emerging biotechnologies.[150] The Oviedo Convention rightly points out in this regard, that *"relevant medical, social, economic, ethical and legal implications"* arising out of developments in biology and medicine must be subjected to public discussion and appropriate consultation.[151] Such a push for public and stakeholder involvement in policymaking is primarily aimed at the protection of fundamental freedoms and rights of individuals; a responsibility inherent to all states and jurisdictions. Another major reason for such calls for public debate is the significant role that stakeholders and the general public play in shaping domestic laws, and in influencing financial markets and commercial trends. Legislation has never been the sole repository of regulatory power and socioeconomic control. In addition to legislation, regulations, and judicial opinions, governance also takes place through informal mechanisms that shape ethical, social, and professional norms in a society.[152]

Public and stakeholder involvement efforts must ideally be comprehensive, transparent, inclusive, methodologically sound, and accountable.[153] This ensures the inclusion of marginalized voices in decision-making and an increase in public trust in governance, which in turn lends legitimacy to the guidelines and policies in question.[154] Thus, policymakers need to

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[148] Greenfield, *supra* note 61.
[149] Ana Iltis et. al., *Public and Stakeholder Engagement in Developing Human Heritable Genome Editing Policies: What Does it Mean and What Should it Mean?* 3(730869) FRONT. POLIT. SCI. 1, 2 (2021), https://doi.org/10.3389/fpos.2021.730869.
[150] NASEM Report, *supra* note 24.
[151] Oviedo Convention, *supra* note 25.
[152] WHO Governance Framework, *supra* note 30.
[153] Iltis, *supra* note 149.
[154] *Id.*

consider alternative approaches to regulation such as the concept of 'Smart Regulation', first introduced in 1998 which refers to a form of regulatory pluralism embracing innovative forms of social control.[155] 'Smart regulation' proposes the use of complementary combinations of different policy instruments,[156] of which self-regulation, voluntarism, information strategies, and harnessing third parties as surrogate regulators to forge public-private enforcement partnerships, are of particular relevance to the topic at hand.

Relevant Stakeholders

Blending positive law with non-binding but voluntarily guidelines and industry standards broadens the letter of the law to a wide range of non-state actors. These non-state actors, including companies, researchers, non-governmental organizations, public-private partnerships, and other parties, then function as decision-makers.[157]

Some of the most important stakeholders in relation to clinical applications of genome editing are undoubtedly the patients who benefit from the advancements in research. These patient groups hold the power to mobilize and finance research, advocate, engage with policymakers and regulators, educate other patients, enable clinical trials, and further advance discussions on ethical considerations.[158] And since researchers, clinicians, patients, and families do not always have the same opinions,[159] it is necessary to engage with different stakeholders in ways that inform their understanding uniquely. Civil society also includes trained scientists and clinical staff, and their concerns must also be heeded during policymaking. Additionally, as mentioned in the CIOMS Ethical Guidelines, stakeholders such as patients, health professionals, researchers, policymakers, public health officials, and pharmaceutical companies benefit from public health research. Hence, it is necessary to ensure ethical research that prioritizes upholding human rights and respect for participants in the study, over any scientific and social justifications of clinical trials.[160]

Social activists and advocates in the fields of disability rights, racial justice, women's health, reproductive justice, queer rights, environmental preservation, and the labour movement, *inter alia*, must be paid special attention to.[161] Similarly, theological and religious concerns also account for crucial factors in stakeholder engagement. Without an inclusive, transparent and multicentered public debate, any attempts at stakeholder involvement would be rendered meaningless.

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[155] Neil Gunningham & Darren Sinclair, *Smart regulation*, in REGULATORY THEORY: FOUNDATIONS AND APPLICATIONS (Peter Drahos ed., 2017).
[156] *Id.*
[157] First International Summit, *supra* note 124.
[158] NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, THIRD INTERNATIONAL SUMMIT ON HUMAN GENOME EDITING: EXPANDING CAPABILITIES, PARTICIPATION, AND ACCESS: PROCEEDINGS OF A WORKSHOP—IN BRIEF, (2023) [hereinafter Third International Summit].
[159] *Id.*
[160] CIOMS, *supra* note 32, Guideline 1.
[161] First International Summit, *supra* note 124.

India's Performance in Stakeholder Inclusion and Public Engagement

India's GTP Guidelines emphasize the importance of public awareness created through periodic interactions with the general public and the industry stakeholders in the country.[162] These guidelines also state, that to be aware of the treatment modalities and risk-benefit analyses concerning emergent technologies such as gene therapies, is a democratic right of the Indian people.[163] In fact, the ICMR has already engaged in dissemination programs with events held in various Indian cities, to promote awareness and adherence to its ethical guidelines among researchers and stakeholders.[164]

The multicultural identities of India's diverse population highlight the need for a portfolio approach, as suggested by Sarojini Nadimpally, a public health researcher.[165] She further states that in this globalized age, local publics must be seen as coproducers of knowledge and agents of change and that we need a bottom-up approach that integrates local knowledge into policymaking, fostering autonomy and participation.[166] This implies the need to educate and engage a larger portion of Indian civil society, particularly those in rural and working-class segments, in decision-making processes for policies on public health interventions.

International organizations such as the WHO, the Organization for Economic Cooperation and Development (OECD), and UNESCO, all have the requisite capacity to bring about comprehensive, inclusive and transparent debate around human genome editing.[167] Additionally, initiatives like the Global Observatory on Genome Editing and the Association for Responsible Research and Innovation in Genome Editing (ARRIGE) also help promote cross-sectoral research and dialogue.[168] The authors thus opine that Indian medical organizations will significantly benefit from collaborations with these global institutions which can help raise public awareness, quell common misconceptions, and foster healthy debate.

Conclusion

India's accelerated growth in the life sciences and pharmaceutical industry, earning it the title of "Pharmacy of the world," is certain to instill a sense of pride in Indians. The spate of deaths of children in low to middle income countries from ingesting Indian-made adulterated medicines, however, will not elicit the same response and rightly so. In a land of stark contrasts and widening socio-economic inequities that manifestly extend themselves to the realm of public health, it is advisable to adopt the precautionary principle over heedless ambition.

As prominent nations like the US and the UK embrace CRISPR gene editing techniques to improve biomedicine and serve the common public, it is suggested that India does the same albeit with a few necessary caveats. Primarily, the Indian government must consider specialized

[162] GTP Guidelines, *supra* note 79, at 61.
[163] *Id.*
[164] Mathur & Swaminathan, *supra* note 104.
[165] Third International Summit, *supra* note 158.
[166] *Id.*
[167] HHGE Report, *supra* note 38.
[168] *Id.*

legislation for the governance of novel genome editing technologies such as CRISPR, instead of relying solely on restrictive guidelines that are less enforceable than laws. Secondly, it is also recommended that the regulatory bodies involved in the governance of CRISPR-based therapies such as the CDSCO, the Ethics Committees and the SECs have more transparency in their decisions that could have a lasting impact on public health. Furthermore, there is a need to accommodate revolutionary technologies like CRISPR through structural changes such as the introduction of gene-editing experts and legal scholars on technology regulation in existing SECs.

Lastly, the authors believe that the staunch opposition offered by many activists and commoners towards the transgenic GMO plants could affect their perception of CRISPR technology and make commercialization of duly approved CRISPR gene therapies difficult in the near future. This problem can be resolved through inclusive stakeholder participation, public engagement and awareness programmes covering genetically, socially, and economically diverse groups of people. In doing so, the conflation of precision technologies like CRISPR with traditional transgenic gene engineering can be avoided and a healthy public discourse based on inter-generational consent, ethical considerations and policy imperatives can ensue.

Acknowledgment

This research was funded by a generous grant from the Thakur Family Foundation. Opinions expressed in the article are independent of any research grants received from governmental, intergovernmental and private organizations. The authors' opinions are personal and are based upon their research findings and do not reflect the opinions of their institutional affiliations.

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