

Genome Editing at the Crossroads: Ethical Dilemmas, Legal Labyrinths, and the Quest for Responsible Innovation in CRISPR Era

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ABSTRACT

CRISPR-Cas9 genome editing has revolutionized molecular biology and medicine by enabling precise, efficient manipulation of genetic material across species. This paper surveys the ethical, legal, and regulatory challenges emerging from CRISPR's transformative potential, particularly in human embryos, germline editing, and therapeutic applications. It examines diverse global regulatory approaches, the complex patent landscape, and critical issues of equity and social justice raised by high-cost treatments and unequal access. Drawing on major case law, international conventions, and governance initiatives such as ARRIGE, the discussion highlights the urgent need for globally coordinated, ethically grounded frameworks that balance innovation with human rights and ecological stewardship. Ultimately, responsible integration of CRISPR technology demands transparent oversight, broad stakeholder engagement, and adaptive legal mechanisms to harness its benefits while safeguarding individual dignity and societal well-being.

INTRODUCTION

CRISPR-Cas9 has rapidly transformed genetic engineering, enabling scientists to edit genes with extraordinary precision across diverse species. This breakthrough technology has accelerated progress in molecular biology, evolutionary research, and disease modeling, fundamentally reshaping biomedical discovery and therapeutic development. Yet, CRISPR's power also generates deep ethical and legal dilemmas—particularly regarding its use in human embryos, where questions of consent, moral status, and global consensus remain unresolved.

The technology's promise in treating genetic disorders, improving crop resilience, and driving innovation is tempered by concerns about unintended consequences, the potential for misuse, and the amplification of inequity and ecological risk. As societies grapple with the blurred boundaries between therapy and enhancement, the ethical challenge is to balance innovation with oversight, ensuring that CRISPR is harnessed for the common good while safeguarding individual rights and social justice.

By exploring the ethical, legal, and governance challenges posed by CRISPR, this paper aims to chart a path toward responsible progress—one rooted in rigorous regulation, transparency, and an enduring respect for human dignity and the natural world.

Ethical Considerations and Bioethics in CRISPR Technology

CRISPR-Cas9, though a relatively recent discovery, has revolutionized molecular biology by enabling precise gene modification across a wide range of organisms—from microorganisms to mammals, including human zygotes. This transformative tool has accelerated research in gene function, evolutionary biology, and disease modeling, opening unprecedented avenues in biomedical discovery.

However, its use in human embryos has sparked intense ethical and legal debate. The central issue revolves around the moral and legal status of the embryo and the absence of a global consensus on “personhood.” Restricting research could stifle advancements in regenerative medicine and totipotent cell studies, yet permitting such research raises concerns about harming embryos without consent. Consequently, global policies vary

widely from outright bans to conditional government authorizations reflecting divergent ethical and legal philosophies.

CRISPR holds immense potential in translational medicine, including immunotherapy, organoid modeling, AI assisted drug discovery, and gene correction in embryos. Despite promising advances, clinical use remains limited, primarily due to concerns over safety, unintended mutations, and long-term effects.

Somatic-cell editing, which targets non-reproductive cells, is ethically comparable to traditional biomedical testing, as it can be ethically managed through informed consent and regulatory oversight. In contrast, germline editing which alters genes passed to future generations poses profound ethical dilemmas. It evokes memories of past eugenic practices, such as those legitimized in *Buck v. Bell* (1927), and raises fears of repeating historical abuses. Nevertheless, advocates argue for evidence based regulation rather than prohibition, emphasizing that even existing therapies (e.g., chemotherapy) carry mutagenic risks. The debate, therefore, centers on balancing innovation with moral responsibility, ensuring that germline interventions are used solely to prevent serious genetic diseases under strict supervision.

Non-therapeutic applications such as enhancing crops, livestock, ecosystems, or human traits pose distinct moral challenges. On one hand, CRISPR can combat global hunger by improving crop resilience and nutritional value; on the other, it risks perpetuating inequity, monopolization, and ecological imbalance.

Gene drive technology, designed to spread particular genes rapidly through populations, offers potential public health benefits (e.g., controlling malaria or invasive species) but also threatens irreversible ecological consequences. Scientists are developing “safety switches” to mitigate these risks, yet the long-term impact remains uncertain.

Human enhancement presents an even more complex ethical dilemma. The boundary between “therapy” and “enhancement” is ambiguous, as definitions of “normalcy” and “disease” are culturally and medically fluid. Enhancement interventions also raise questions of personal autonomy and constitutional liberty whether individuals should have the freedom to modify themselves or their offspring in pursuit of perceived perfection.

CRISPR technology represents both a revolutionary scientific tool and a profound ethical challenge. While it holds the promise of eradicating genetic diseases, enhancing agriculture, and transforming medicine, it simultaneously confronts humanity with questions about autonomy, justice, and moral limits. The path forward lies not in fear-based prohibition but in rigorous, transparent, and ethically guided research—supported by international cooperation and evidence-based policy. Only then can society harness CRISPR’s potential responsibly while upholding human dignity and ecological integrity.

Regulatory Framework And Governance

The governance and regulatory landscape surrounding CRISPR technology is rapidly evolving. As an advanced genome-editing tool, CRISPR enables precise modification of genetic material, driving innovation in personalized medicine and the treatment of genetic disorders. However, the ability to alter human DNA also raises profound ethical, legal, and policy challenges, demanding robust oversight to ensure safety, accountability, and respect for human rights.

In the United States, CRISPR-based applications are primarily regulated by the Food and Drug Administration (FDA) and the National Institutes of Health (NIH). The FDA oversees CRISPR therapies under its framework for human gene therapy products, which includes the requirement for Investigational New Drug (IND) applications to ensure clinical safety and efficacy before approval. The NIH, through Institutional Biosafety Committees (IBCs), mandates biosafety reviews to guarantee that research involving recombinant DNA complies with established safety and ethical standards.

Currently, germline editing for reproductive purposes remains prohibited in the U.S., reflecting ethical concerns about heritable genetic modification. However, somatic cell applications, which do not affect future generations, are approved under strict regulatory scrutiny. For instance, the FDA’s approval of Casgevy (for the treatment of

sickle cell disease) represents a major milestone in therapeutic genome editing, showcasing a model for responsible clinical application.

Globally, regulatory approaches to CRISPR governance vary widely, reflecting differing cultural values, legal traditions, and ethical frameworks.

The European Union (EU) is developing harmonized genomic regulations that aim to balance scientific innovation with strong ethical safeguards, ensuring the protection of individual rights and biosafety. In contrast, the United Kingdom and China have adopted frameworks that permit limited germline research under stringent governmental supervision. The UK's Human Fertilisation and Embryology Authority (HFEA), for instance, allows CRISPR research on embryos up to 14 days post fertilization, while China has strengthened ethical oversight following prior controversies involving embryo editing.

Such diversity in governance demonstrates the global struggle to reconcile scientific potential with ethical restraint, highlighting the urgent need for internationally aligned standards.

Within healthcare law, CRISPR challenges traditional notions of liability, informed consent, and equitable access. Therapies developed through genome editing must adhere to the foundational principles of patient safety, bioethics, and social justice, which healthcare regulators are responsible for upholding.

As CRISPR transitions from research to clinical practice, regulatory bodies must ensure that consent procedures are comprehensive, risks are transparently disclosed, and patients are protected from exploitation or undue harm. The future of CRISPR regulation lies in globally coordinated governance that integrates scientific innovation with human rights protection and public health priorities.

Legal Issues In Clinical And Research Contexts

Legal challenges associated with CRISPR span multiple dimensions, including patient safety, informed consent, research ethics, and intellectual property rights. Clinical Liability and Safety with subject to Off-target mutations and unintended genetic effects pose significant safety concerns, potentially leading to claims of medical negligence or malpractice under tort law. Physicians and researchers have a legal duty to obtain informed consent, ensuring that participants are fully aware of potential risks and uncertainties. Failure to meet these obligations not only constitutes ethical misconduct but also violates established legal standards governing medical research.

Ethical lapses underscore the necessity for Institutional Review Boards (IRBs) or equivalent ethics committees to approve CRISPR studies before initiation. Such oversight ensures compliance with principles of beneficence, non-maleficence, and respect for autonomy, forming the backbone of lawful and ethical biomedical research. CRISPR has also become the focus of extensive patent litigation, particularly between institutions such as UC Berkeley and the Broad Institute of MIT and Harvard. These disputes determine who holds the legal right to develop and commercialize CRISPR-based technologies, directly influencing the pace of innovation and the accessibility of therapies. Restricted access to patented CRISPR tools risks widening the gap between public and private research institutions, undermining the principle of scientific equity that underpins global healthcare law.

Looking forward, CRISPR governance must expand to address new legal domains, including data ownership, cross-border clinical trials, and genetic privacy. As genome editing moves into mainstream medicine, regulators will need to define who controls genetic information, how cross-jurisdictional research is monitored, and how patients' data are protected from misuse. Ultimately, CRISPR regulation should aim for responsible innovation—enabling progress while safeguarding human welfare, dignity, and ecological balance. International cooperation, transparent policymaking, and continuous ethical reflection will be key to ensuring that CRISPR technology evolves within a just and sustainable framework.

Intellectual Property, Patent Law, And Equity In CRISPR Technology

The intersection of intellectual property (IP), patent law, and CRISPR technology represents one of the most transformative yet contentious areas in modern healthcare law. CRISPR's unprecedented precision in gene

editing has reshaped biomedical research and clinical medicine, yet the question of ownership—divided among competing research institutions—raises pressing concerns over innovation, accessibility, and ethical application. As the technology transitions from laboratory research to therapeutic use, the legal mechanisms that govern ownership and access are increasingly being tested against broader principles of bioethics and social justice.

The patent disputes surrounding CRISPR revolve primarily around competing claims by the University of California, Berkeley (UC Berkeley) and the Broad Institute of MIT and Harvard. Both institutions asserted invention rights over the CRISPR-Cas9 system, but the U.S. Patent Trial and Appeal Board (PTAB)—and later the Federal Circuit—ruled in favor of the Broad Institute, granting it patents covering the application of CRISPR in eukaryotic cells. UC Berkeley retained rights over its use in prokaryotic organisms, such as bacteria.

This fragmented ownership structure has resulted in divided constituent rights, complicating global licensing and limiting open scientific collaboration. The Broad Institute's patents allow it to license CRISPR for human gene therapy, effectively granting it significant control over access to therapeutic applications. This patent landscape underscores a critical tension between proprietary control and the collective advancement of science.

CRISPR also reignites debate over the patentability of biological substances. Following the landmark case *Association for Molecular Pathology v. Myriad Genetics* (2013), the U.S. Supreme Court ruled that naturally occurring DNA sequences cannot be patented, as they are products of nature, whereas synthetic DNA (cDNA) may be patented as a human invention. This legal distinction preserves a delicate balance: it rewards innovation while preventing the monopolization of fundamental biological information.

In the CRISPR context, this precedent helps define the boundaries of what constitutes an “invention.” By recognizing synthetic or modified biological tools as patentable, while excluding unaltered genetic material, the law seeks to balance investors' incentives with public access, ensuring that gene-editing technologies advance medical progress without being unduly commercialized or restricted.

Within medicine, CRISPR patents determine who can develop and market gene-editing therapies, which in turn influences drug pricing, research inclusivity, and patient access. Concentrated IP ownership risks creating de facto monopolies, restricting the range of CRISPR nucleases available to smaller biotech firms and academic researchers. Such monopolization not only stifles innovation but also impedes the diffusion of life-saving treatments.

To address these barriers, policy proposals include creating patent pools—shared licensing platforms that consolidate multiple patents to simplify access—and promoting global harmonization of gene-editing IP law. These measures could facilitate fairer licensing practices, reduce litigation costs, and promote equitable research collaboration across borders.

Incorporating CRISPR within healthcare law necessitates redefining traditional IP principles to align with contemporary bioethical imperatives. Patent systems must evolve beyond rewarding mere novelty; they must also reflect commitments to patient welfare, genetic diversity, and equitable access. Future legal frameworks should ensure that patenting stimulates scientific innovation without undermining the humanitarian principles of medicine. This calls for an ethical recalibration of patent law—anchored in responsible innovation and public good rather than profit maximization.

Equity, Justice, And Access

The CRISPR-Cas9 revolution raises deep questions of equity and distributive justice, particularly due to the high cost and complexity of resulting therapies. This risk of creating a “genetic divide” is already evident in the first approved CRISPR-based treatment, Casgevy, a cure for Sickle Cell Disease (SCD) approved in the U.S. and U.K. While medically groundbreaking, Casgevy's cost—approximately \$2.2 million per patient—renders it inaccessible to most, especially since SCD disproportionately affects populations in Sub-Saharan Africa and other low-income regions.

Such pricing structures violate the spirit of the “right to health” enshrined in the International Covenant on Economic, Social and Cultural Rights (ICESCR), which establishes a moral and legal duty for states to ensure

universal access to essential healthcare. When potentially curative therapies become luxuries for the affluent, the result is a systemic inequity that undermines the foundational values of medical justice.

Justice concerns also arise from the biases in genomic data underpinning CRISPR research. Over 80% of large-scale genomic datasets currently derive from individuals of European ancestry. This underrepresentation of racial and ethnic minorities skews the development of CRISPR tools, potentially reducing their efficacy or safety for non-European populations. Consequently, existing health disparities risk being replicated at the genomic level, further entrenching inequality under the guise of precision medicine.

Moreover, the 2018 He Jiankui case—involving CRISPR-edited babies engineered for HIV resistance—exemplifies the ethical and justice dangers of unregulated enhancement. If genetic enhancement (e.g., intelligence or physical traits) were permitted, access would likely be restricted to wealthy elites, creating heritable biological class divisions that contravene the principles of social and intergenerational justice.

Existing statutory and regulatory frameworks focus primarily on safety, consent, and misuse, but insufficiently address issues of equitable access. For instance, in the U.S., the Dickey-Wicker Amendment prohibits federal funding for research involving germline editing—enforcing ethical caution against heritable modification. However, agencies like the FDA assess products based solely on safety and efficacy, not affordability. This creates a regulatory gap where market dynamics dictate accessibility, allowing multi-million-dollar therapies to proliferate without mechanisms ensuring affordability.

Bridging this gap requires proactive legal and policy interventions. Governments could adopt tiered pricing, compulsory licensing, or public-sector investment to ensure that CRISPR-based therapies align with the broader goals of global health equity and social justice. Without such measures, CRISPR risks deepening—not healing—the divide between the genetically privileged and the rest of humanity.

International And Comparative Perspectives

The international governance of CRISPR gene editing is characterized by a deep and persistent divide in regulatory philosophies, creating a fragmented global landscape. The primary distinction lies between product-based and process-based approaches to regulation.

Countries such as the United States, Canada, and Japan adopt a liberal, product-based framework, which focuses on the characteristics of the final product rather than the method used to create it. Under this approach, gene-edited organisms are exempt from stringent genetically modified organism (GMO) laws if no foreign DNA is introduced. This regulatory model, particularly influential in agricultural biotechnology aims to accelerate innovation, enabling the development and commercialization of crops with desirable traits such as pest resistance or climate adaptability with minimal bureaucratic delay.

In contrast, the European Union (EU) adheres to a restrictive, process-based model, treating all gene-edited organisms as GMOs regardless of whether the end product contains foreign genetic material. This framework, grounded in the precautionary principle, prioritizes ecological safety and consumer protection over rapid market adoption. While it ensures higher ethical and environmental scrutiny, it also slows innovation, creates regulatory uncertainty, and generates trade friction with jurisdictions that have more permissive standards.

This divergence between product-based and process-based systems underscores the absence of a unified global approach to genome editing and has prompted ongoing efforts toward international harmonization. Without coordinated regulation, the global movement of scientific knowledge, agricultural products, and medical technologies remains subject to conflicting legal interpretations and compliance barriers.

The most ethically sensitive domain in comparative regulation concerns human gene editing, particularly the distinction between somatic and heritable germline editing (HGE).

Somatic cell editing, which targets non-reproductive cells and does not affect future generations, is broadly accepted as a legitimate form of gene therapy. It is generally regulated within existing clinical and biomedical

frameworks—such as the U.S. Food and Drug Administration (FDA) system for investigational therapies—ensuring oversight of safety, efficacy, and informed consent.

In contrast, heritable germline editing, which alters reproductive cells and transmits modifications to offspring, faces near-universal legal prohibition. This global stance is underpinned by a robust ethical firewall reflected in international legal instruments, most notably the Council of Europe's Oviedo Convention on Human Rights and Biomedicine (Article 13), which explicitly bans interventions that aim to modify the human genome in a heritable manner.

The international consensus against HGE was reaffirmed following the 2018 He Jiankui incident in China, where CRISPR was used to create genetically modified babies purportedly resistant to HIV. The global backlash to this event prompted renewed calls for stronger international governance, stricter enforcement of ethical standards, and the reaffirmation of the boundary between therapeutic intervention and germline enhancement.

The foundation of international prohibitions on heritable gene editing lies in human rights law, which provides the ultimate ethical and legal constraint on the use of genome-editing technologies. Central to this framework is the protection of the autonomy and dignity of future generations, who cannot provide consent for permanent genetic alterations that will define their biological identity.

Permitting heritable gene editing, critics argue, would violate the human right to an unaltered genetic identity, effectively transforming reproduction into an act of genetic design. Such a shift risks normalizing market-driven eugenics, in which genetic enhancements become commodities accessible primarily to the wealthy. This would deepen existing social and genetic inequalities, entrench discrimination against individuals considered “unmodified,” and erode the egalitarian basis of human rights and justice.

The challenge for the international community lies in developing a coherent, harmonized framework that accommodates scientific innovation while preserving fundamental human rights. Future regulatory alignment will require sustained dialogue between states, scientific institutions, and human rights bodies to establish shared principles of transparency, accountability, and ethical oversight.

Ultimately, CRISPR's global governance must transcend national boundaries, recognizing that genetic interventions carry cross-border ethical implications. Only through internationally coordinated governance, anchored in evidence-based policy and human rights can the world harness CRISPR's transformative potential responsibly, ensuring that genomic innovation serves humanity as a whole rather than the privileged few.

Future Directions And Policy Reform

As CRISPR technology continues to advance, calls have intensified for the creation of a comprehensive global framework to address the profound ethical, legal, and societal implications of genome editing. The rapid pace of scientific innovation has outstripped existing governance structures, underscoring the need for a coordinated international approach that transcends national boundaries and disciplinary silos.

One of the most notable efforts in this direction is the Association for Responsible Research and Innovation in Genome Editing (ARRIGE), established in 2019 through the collaboration of European scientists. ARRIGE seeks to promote ethical responsibility, transparency, and global inclusivity in the governance of genome editing technologies such as CRISPR. By fostering international dialogue among scientists, policymakers, and civil society, ARRIGE represents a critical step toward building shared principles for responsible innovation.

Complementing this initiative, scholars Sheila Jasanoff and Benjamin Hurlbut have proposed the establishment of a Global Observatory for Gene Editing—an international and interdisciplinary platform designed to ensure that moral deliberations surrounding gene editing are not confined to the scientific community alone. They argue for a governance model comparable to those addressing human rights and climate change, emphasizing that gene editing raises universal ethical questions about what it means to be human. Such a framework would bring together diverse cultural, geographic, and disciplinary perspectives, embedding ethical reflection within the global governance of biotechnology.

Together, ARRIGE and the proposed Global Observatory signify a paradigm shift from reactive regulation to anticipatory governance—one that seeks to shape the ethical and legal boundaries of CRISPR before misuse or inequality takes root. These initiatives highlight the growing recognition that science cannot self-regulate in isolation; instead, it must operate within democratically legitimate structures that reflect collective human values.

Moving forward, the development of comprehensive ethical and regulatory guidelines, both nationally and internationally is essential. Policymaking should involve broad stakeholder participation, including governments, research institutions, civil society, and affected communities. Such collaboration will be vital for providing clear direction to federal funding agencies, institutional review boards (IRBs), and principal investigators, ensuring that research integrity and ethical compliance remain central to scientific practice.

Ultimately, the future governance of CRISPR will depend on the establishment of legally binding and ethically grounded frameworks that balance innovation with moral responsibility. Effective oversight mechanisms rooted in accountability, transparency, and inclusivity will determine whether genome editing evolves as a tool of human advancement or a source of ethical division. The path forward, therefore, lies in cultivating a global governance architecture that aligns scientific progress with human dignity, justice, and collective responsibility.

CONCLUSION

CRISPR technology occupies a pivotal crossroads in biomedical science, promising revolutionary advances in disease treatment, gene correction, and agricultural productivity. Yet, this same tool challenges longstanding ethical principles, legal norms, and social values, requiring careful reflection and strategic regulation. The global response to CRISPR demonstrates that no nation or discipline can address these issues in isolation; robust frameworks must balance scientific innovation with protection of human rights, ecological integrity, and equitable access.

As the technology evolves, the risks of genetic inequity, unregulated enhancement, and cross-border ethical violations intensify, making international cooperation and anticipatory governance critical priorities. Effective oversight, grounded in transparency, patient safety, and social justice, should ensure that life-changing therapies become universally accessible and that scientific progress aligns with humanity's deepest moral commitments.

Ultimately, the future of CRISPR will depend on society's willingness to integrate ethics, law, and public participation into the scientific enterprise. By forging global consensus and adapting legal institutions to emerging challenges, we can guide genome-editing innovation toward outcomes that honor both individual dignity and collective responsibility.