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GENETIC EDITING AND THE LAW: NAVIGATING CRISPR TECHNOLOGIES IN A GLOBAL CONTEXT

Irtiza Kashif Siddiqui[*1], Dr. Tansif Ur Rehman[2], Dr. Aisha[3]

[*1]*Department of Law, Dadabhoy Institute of Higher Education, Pakistan*
[2]*Teaching Associate, Department of Sociology, University of Karachi, Pakistan; Visiting Faculty, Department of Law, Dadabhoy Institute of Higher Education, Pakistan*
[3]*Women Medical Officer, Civil Hospital Naushahro Feroze, Pakistan*

[*1]irtizasiddiqui737@gmail.com, [2]tansif@live.com, [3]aishasolangi786@gmail.com

[2]0000-0002-5454-2150

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Corresponding Author: *
Irtiza Kashif Siddiqui

Abstract

The genetic editing, and specifically the development of CRISPR-Cas9, the scientific potential to make changes in genomes in a highly specific and efficient way has been significantly increased, transforming the research in the fields of medicine, agriculture, and environmental science. These fast developments bring up complicated ethical, legal, and social issues that traverse national borders and require a unified governance solution to make sure that the benefits are distributed and risks are reduced. The article compares the world regulatory frameworks of up-and-coming technologies in the field of gene editing and compares two opposite methods of how the nation should approach the issue, both in the realm of somatic application, aimed at treating the disease in a particular patient, and in the realm of germline interventions, which can alter heritable features and thus have long-lasting consequences on the society. It also takes into account the examples of the past, like the Asilomar conference in the early years of self-regulation, and recent years, international guidelines, to find the right balance between innovation and population protection. It discusses the basics of bioethics, human rights, and risk governance, and evaluates the impacts of different policy instruments on safety, fairness, and intellectual property relations and enforcement. The study cites such crucial governance concerns as regulatory fragmentation, scientific ignorance, inequitable access, and tracking cross-border action issues, and the opportunities of therapeutic breakthroughs, agricultural resilience, and ecological governance in responsible stewardship.

Introduction

CRISPR-Cas9 gene-editing technologies have now had the potential to grow with spectacular opportunities in the areas of medicine replacers, agriculture, and biotechnology (bio-hacking) (Wiley et al., 2024). Their growing accessibility and effectiveness, combined with accuracy, are allowing them to be used outside of the conventional laboratory environment, resulting in an increase in ethical, social, and governance concerns (Cadigan et al., 2024). Although somatic genome-editing cures are on the verge of clinical use and the health advantages are unquestionable, germline or heritable editing is much more

contentious in terms of consent and intergenerational fairness, and ecological hazard and social equity (Biswas, 2025; Niazi, 2023). The rejuvenated ethical discussion and scientific development are essential requirements that are supported by such progress.

The regulatory provisions on genome editing are highly disjointed. Others are used to add gene-edited organisms and human therapies to current legislation (Wang, Shang, & Zhang, 2023), but others use more conservative approaches, based on either existing GMO or biosafety regulations, which can lead to potential regulatory gaps (Vengadesen et al., 2025). This heterogeneity has the potential to promote CRISPR tourism and make it challenging to regulate globally. Adaptive, principle-based, and globally coordinated regulatory frameworks are also required to strike a balance between innovation, safety, equity, and social responsibility (Nicol et al., 2023).

Research Justification

The rationale of this study is that the CRISPR technology has rapidly developed traction in other areas (clinical trials, agricultural innovations, and even planned ecological applications), and that the absence of regulation has created a major ethical risk as well as a legal ambiguity. Although various countries and global policies have developed, significant loopholes in their implementation, the possibility of monitoring and even the provisions of the policies remain, creating a chance of unethical experimentation or unequal access to potentially beneficial technologies. The most prominent of such cases is the birth of gene-edited babies in 2018, which demonstrates the effect of the absence of any control on an international level and, consequently, introduces the notion that a powerful and efficient review mechanism is necessary, as well as global regulation.

Access to intellectual property is also not fair since intellectual property concentration is in the hands of a few institutions. This kind of concentration may limit the engagement of researchers and communities in less resourced contexts, and further raises concerns about the issue of equity and international justice. In order to address these challenges, one will need to think about the opportunities of licensing and collaboration deals, open-access frameworks that will ensure fair distribution of scientific and technological benefits, and facilitate innovation and sustainable use.

The study aims to provide effective governance solutions to policymakers by integrating historical knowledge, morals, and comparative law perspectives. These avenues are targeted at advancing scientific advancement and safeguarding the rights of individuals, communities and ecosystems. Such would give the governance systems the opportunity to monitor the rate of change of technological development made to take a socially-responsible, ethically-justifiable, and globally equitable route.

Literature Review

Genome-editing governance has grown and developed in scholarship in recent years, past mere speculation to enter into in-depth engagement with a scientific and legal gray zone alongside societal ramifications. To begin with, the scientific-ethical literature has highlighted the potential as well as the danger of CRISPR and other associated genome-editing technologies. For example, a review of CRISPR-Cas9 editing of human embryos shows that safety is still a concern (for example, off-target mutations), the long-term safety is still unknown, and the ethical issues surrounding editing the human genetic code are still not fully understood. Preventive steps should be taken before any clinical use (Wiley et al., 2024).

Simultaneously, computational and methodological analyses of CRISPR guide design offer informative perspectives on how to enhance precision of editing, reduce off-target effects, and enhance efficiency. What computational and methodological strategies researchers should undertake when thinking of clinical or germline use (Giner et al., 2023). In a broader sense, the emergent biosafety-oriented scholarship raises awareness about dual-use risks of gene-editing and synthetic biotechnology, with the view that regulatory and safety frameworks have not kept pace with the rate of innovation.

Second, comparative-legal and regulatory studies report that country and regional reactions to genome editing are very fragmented. A global survey of the regulation of genome-editing products (plants, animals, and derived bioproducts) as of 2023 shows the broad range of variation among countries. Other countries have altered their regulations regarding GMOs and biosafety and some countries continue with the old regulations. Clear laws and methods to enforce them are lacking even in many countries (Wang, Shang, & Zhang, 2023). Simultaneously, when examining the manner in which Latin America approaches the issue of agricultural gene editing one will realize that not all things are a straightforward path. It becomes obvious that certain policy windows and actions of certain policy entrepreneurs on the regulation of the country, suggests that regulation is not only reactive but also uneven and depends on the political situation (Zarate et al., 2023).

In the meantime, a 2025 article on the regulation of gene-edited crops suggests a precautionary and adaptive governance framework based on the principle-driven approach, especially due to the high rate of technological diffusion and uncertainties about the long-term ecological impacts (Vengadesen et al., 2025). These discussions highlight how the heterogeneity in regulation, or even regulatory emptiness, opens opportunities to cross-border genome-editing tourism, legal arbitrage, and skewed safeguards of societal safety and social justice.

Third, governance and policy scholarship demands multi-layered, adaptive, and globally coordinated systems to deal with the two-fold issue of innovation and risk. A survey of scientists and governance experts on the topic of heritable human genome editing shows that there is a plurality of opinions, with many supporting the idea of research with stringent control, but strongly expressing their worries about social justice and equity, as well as the capabilities of governance (Cadigan et al., 2024). To that end, researchers suggest that good governance ought to be a synthesis of statutory law, soft-law mechanisms, moral scrutiny, open registries, and stakeholder consultation so that it is responsive to scientific change, but does not suffocate useful uses (Conley et al., 2025).

The same school of thought opines that the world needs coordination and equity-oriented governance to curb the occurrence of genetic inequality and make sure that the benefits of genome editing are fairly distributed among societies (Biswas, 2025). Overall, the new literature is shades of grey and quite lifelike. CRISPR and genome editing are potentially transformative, but their ethical, legal, and social implications require regulatory clarity, effective governance, engagement by all, and international collaboration prior to large-scale application.

Historical Context of Genetic Editing

Genetic modification aroused the interest of the governments as early as the scientific community attempted to put risky technologies under control, preceding the implementation of formal legislation. In 1975, various molecular biologists, jurists, and individuals in the society of public health convened a conference named the Asilomar conference to discuss the potential risks of recombinant DNA. Confinement and safety as a paradigm proved to be a model of self-regulation of science, which proves that scientists can influence norms without government intervention (Dimond et al., 2023; Scheffler, 2025). This was also not just to the local and regional regulations, but it also brought broader social expectations that biotechnology should progress slowly and responsibly for the population (Zou et al., 2025). The history of Asilomar still influences modern debates on preemptive governance and the presence of scientific communities in the governance of new technologies.

In the 2010s, the technical cost of the CRISPR-Cas9 system was radically reduced by repurposing the system into a useful gene-editing system, and the technical cost of the system controversially fueled the debate on human genome modification. The world was shocked when the first gene-edited babies were born in 2018. It showed that there were no rules or morals (Wang, Mu, Yan, Tang, & Jiang, 2023). In response, most

of the countries modified or increased the control measures and provided additional biosecurity, ethical review, and legal liability (Scheffler, 2025; Zou et al., 2025).

Among the common themes that the episode raises is that genome editing technology tends to move faster than regulations, and that trend underscores the need to establish a proactive and responsive regulation that can prioritize innovation and safety, human rights, and social responsibility (Conley et al., 2025). Such incidents show that there should be international coordination and the involvement of people in the formulation of policy frameworks that could serve both in dealing with technical risks and social issues.

Theoretical Context of Genetic Editing

The legal principles of genome editing are based on a number of interdisciplinary theories, including bioethics, human rights theory, and risk-governance scholarship. The main tools of evaluation to decide on interventions that may be implemented in the clinical setting and in research are the principles of autonomy, beneficence, absence of maleficence, and justice. These principles can be used to help enlighten discussions of patient welfare, informed consent, and equitable sharing of advantages and disadvantages, as well as the challenges faced by the new technologies.

The underlying dignity of the human rights aspects adds to this background of dignity, the inviolability of the human body of people, and the principle of equal access to science. States, in the event that you have to file for bankruptcy, are expected to be responsible for thwarting negative or abusive uses of genome editing, to provide an enabling atmosphere in which citizens can enjoy the benefits of safety and equity. The advantages of biomedical inventions. This is because the technological influence should be coupled with the protection against discrimination, exploitation, or social inequalities, since this is one of the ways of recognizing this. Risk-governance theory proposes another aspect of thinking, that is, the focus on the irreversibility, uncertainty, and adaptivity of regulation.

Those who carry out research in this area are convinced that the scientific advancements that take place in these fields are at a high rate and require regulating regimes that are flexible, clear, and can be updated as knowledge evolves. Democratic theory adds to this view that legitimacy needs to be inclusive in the process. The culturally responsive consultation and the provision of mechanisms to address it were the three areas that were of particular interest, as these perceptions create the foundation for an ethical, participatory, and responsive governance formed around a model that is aware of the scientific change happening in the modern world. Together, these perceptions form the basis of an ethical, participatory, and responsive model of governance that is attentive to modern scientific changes.

Laws Regarding Genetic Editing

Treatment of genome editing in the legal framework has been very diverse depending on the jurisdiction, and somatic and germline interventions are often separated. The examples of the regulatory frameworks and their implications in relation to research and clinical practice are key:

1. **Council of Europe - Oviedo Convention**: It is a convention that deals with the precautionary principle and human dignity. It leans towards forbidding hereditary alteration of the genome, but permits controlled therapeutic studies, which embody a governance paradigm based on human rights.

2. **United Kingdom - Human Fertilisation and Embryology Act (1990, amended 2008)**: In the UK, a licensing system is adopted by the Human Fertilisation and Embryology Authority (HFEA). A mitochondrial replacement therapy represents one of the tangible procedures, which can be conducted in the frames of this statute, and this is how it is possible to realize that clear regulation can allow practicing safely and limiting the possibilities of abuse.

3. **United States - Federal regulation**: The U.S. does not explicitly have any federal law on germline editing. There is a separation of monitoring between agencies, e.g., the Food and Drug Administration (FDA) and the National Institutes of Health (NIH). Administrative direction and restrictions on federal funds give guidance on practice and create flexibility and a lack of transparency in practice.

4. **China-Ethical and criminal laws**: China further strengthened its regulatory framework through administrative punishment, increased attention to ethical behavior, and integration of criminal liability in using unapproved germline editing, which is a sign of increased strict state regulation.

5. **Low and middle-income countries**: Most countries are either governed by non-binding principles or well regulated, and this can expose them to international regulation, in addition to putting them at even greater risk at the hands of cross-border unethical practices.

6. **International governance**: International authorities like the World Health Organization propose world registries, moral norms and standardized norms. Though there is no binding international treaty as yet, a temporary moratorium on clinical germline editing to establish international agreement has been proposed by some policymakers

Challenges for Genetic Editing

CRISPR and other genome-editing regulations are faced with a myriad of overlapping issues, such as scientific insecurity, patchy regulations, and socio-political complexity. One of the main problems is the scientific uncertainty. Technical issues such as editing the wrong target, mosaic, immune reaction, and long-term ecological consequences that might occur in the future and are difficult to predict complicate the risk assessment. The uncertainties justify the adoption of powerful and dynamic surveillance systems that will be able to revise the standards of safety as new facts emerge in the course of time. Lack of such systems would mean that decision-makers would be at risk of being either overly critical of what otherwise would have been potentially promising innovations or letting applications that are not safe through would pass on causing significant ethical and practical problems to both researchers and policymakers.

A second group of difficulties is regulatory heterogeneity and enforcement constraints. The availability of inconsistencies in national law, administrative guidance, and inspection capacities permits researchers, patients, and experimental uses to cross-nationally, which could be a cause of so-called CRISPR tourism. This is the shortage of adequate staffing, legal framework, or facilities to regulate laboratories, clinical trials, and commercial uses, which is typical in most countries. The intellectual property being centrally controlled by the original CRISPR patents also makes it harder to govern by restricting access, steering research, and potentially hurting those parts of the world with fewer resources.

Also, the general population still lacks trust in the regulation of genetic editing; cultural beliefs and high-profile scandals often have a considerable impact, which is why it is important to make sure that the regulation is clear and connected with the meaningful participation of different stakeholders. Lastly, there are ethical and ecological other governance issues that are a concern. While the failures of human enhancement, inter-generational responsibility, and trade-offs of risks and benefits, which are acceptable, make consensus building within and between countries more difficult.

Gene drives and other ecological applications pose risks, which are trans-regional and trans-ecosystem in nature, needing to be regulated multilaterally, well-defined liability, well-thought out containment measures. To resolve these scientific, regulatory, social and ethical issues, the world needs international norms that are standardized, discourse, more enforcement capacity, more equitable intellectual property practices to ensure socially and ethically responsible, fair and the global provision of an acceptable use of genome editing technology.

Opportunities for Genetic Editing

Even though there are a lot of risks involved but CRISPR technologies could change in many respects, like medicine, agriculture, conservation, and economic development. The potential of somatic gene-editing therapies is truly remarkable in the medical field, and early clinical results for diseases like sickle-cell disease and beta-thalassemia have had long-lasting positive effects on patient health. These discoveries imply that wisely directed applications of gene editing can offer significant and long-term benefits, potentially reducing the treatment burden and expanding treatment options to conditions previously having limited or no effective options. Besides treatment, genome editing can be used to accelerate precision medicine, whereby treatment-focused interventions can be tailored to address the specific genetic makeup of the patient, thus improving overall patient outcomes.

Gene editing may be applied to the agricultural industry to produce disease-resistant, climate-resistant, or nutritionally enhanced crops without inserting foreign DNA. These inventions would reduce the hurdles posed to the conventional genetically modified organisms, as they may be central in combating food insecurity in the neediest regions. Genome editing has the ability to empower the food systems of the whole world by improving crop output and resilience, and agricultural sustainability. Improved environmental uses can also be found. Gene drives may be considered as a technique to control vectors to decrease the spread of malaria or to control invasive species that may harm ecosystems. These strategies, together with good safety and containment measures, can lead to large-scale public-health benefits and biodiversity protection. The economic opportunities of CRISPR technologies are also important. Advancement of gene-editing technologies makes it easier to develop the biotechnology industries, enhance the research facilities, and establish new possibilities regarding the cooperation between the state and the business. The changes in the policy, including the patent pools, public-interest licensing, and open-science platforms, can be used to expand access, spur innovation, and make the fruits of these technologies more fairly distributed. These opportunities come together to form a strong basis in governance. It is about more than just rules, it's about making sure scientific progress serves people, stays ethical and reach sustainable development targets.

Discussion

The comparative analysis suggests that none of the regulatory models is adequate to control genome editing on a worldwide level. Fragmentation among the National systems is the real risk. It creates opportunities for regulatory loopholes and, unfortunately, an inequitable distribution of genome-editing advancements. In order to correct this, a flexible, polycentric model is needed that connects to provide global guidance and regional and local laws to support progress that is fair and ethical for all. A model such as this will enable striking a balance between safety and innovation, enabling a flexible but principled supervision that would be able to respond to the rapid advances of science.

There must be concrete facilities and equipment for this approach to work. The most important ones are the establishment of a global registry of research on human genome editing, alignment of ethical assessments, financial support to enhance regulatory ability in resource weakened areas, and fair intellectual property resources that expand access to CRISPR technologies. New uses that involve cross-border impacts, such as gene drives, are especially significant and need to be coordinated regionally, such as through the common assessment of their environment. The mechanisms of liability and risk containment measures are presented. The mechanisms of liability are presented, as are containment measures to mitigate risk.

To avoid the capture of governance by special interests, ensuring legitimacy and trust, all-inclusive engagement of a broad spectrum of stakeholders will be necessary for a large part of the population, including patients, communities, indigenous groups, scientists, and ethicists. This participatory and a pragmatic approach is a

potential and morally responsible approach to regulating CRISPR on a global level by gradually and with robust national oversight, harmonizing international standards, and improving upon innovation without compromising the social and environmental well-being.

Conclusion

While the CRISPR technologies are revolutionizing medicine, agriculture, and environmental management, they also raise complex ethical, legal, and social issues that cross borders. The current system of national regulation is very discontinuous, ranging from the strict prohibitions to the less stringent agency-based systems, thus leading to inconsistency and regulatory arbitrage. A biocentric, flexible governance framework that is based on bioethical ideals, human-rights obligations, and open supervision offers a viable way of striking a balance between innovation and precautions.

A good governance system involves setting international minimum standards, good ethical reviews, reporting systems, and well-coordinated policies to deal with cross-border implications, especially on ecological applications that have regional impacts. Fair and equitable access and abuse-avoidance will be critical to consider in relation to IP arrangements, substantial involvement of the population, and the capacity to fully evaluate the environmental risks.

Recommendations

The proper regulation of CRISPR and human genome-editing technology should be a collective effort, both on the international and national levels. Creating a professional body in the name of international agencies, like the World Health Organization or UNESCO, can serve as a bare minimum of guidelines of international regulation, which would include a compulsory registration of all studies and human genome clinical trials. It should do that on the national level with adaptive regulatory systems by establishing periodical review systems that are linked to scientific milestones that ensure the scientific standards of law are synced with technology development. There is some evidence that it is necessary to reinforce non-disclosure and accountability through mandatory reporting and mandatory registration of experiments, and sanctions for non-compliance. The institutions need to strengthen and have independent ethical review boards and multidisciplinary controls as a way of reviewing sensitive research, particularly research involving embryos or germline interventions.

Reasonable and global equality are the key ingredients to accountable leadership. The various intellectual property practices can be crafted to support inclusivity through patent pools, nonexclusive licensing, or tiered pricing, and by making sure that the low-resource regions are included. The strengthening of regulations, training of professionals, and raising awareness of the population about CRISPR will increase control and awareness of these technologies in society. The global nature of ecological tools like gene drives needs to be taken into account, including contingency planning and liability forums. It is engaging in contact with people, global investments, organized, open-data projects, and more all of which help to consider different perspectives, make information accessible, and earn the trust of the people. These measures lead to a viable, equitable, and clear system of governance that will foster innovation without sacrificing the ethical, social, and ecological values.

Research Limitations

The study is built on an important survey of secondary sources, institutional reports, policy analysis, but no empirical data (interviews, field observations, case studies), which takes jurisdictions into account. Therefore, it may fall short of capturing the richness of informal regulatory behavior, on-the-fly decision-making regarding policy, or context-specific enforcement mechanisms that support real-life practice. Depending on the country, there can be significant differences in the availability of data, which can lead to a distortion in the comparative results, as it can be in favor of the countries with better data availability and regulatory systems.

Quick scientific advancement and changing administrative direction also contest fixed judgments; that is, the findings might need frequent review to be valid. The legal/institutional route of the research might also fail to include an orientation of the community that may require more qualitative research, or moral order and community values. Lastly, even though the polycentric approach to governance has been theoretically argued to be a suitable and meaningful model, it has not yet been tested in practice with pilot projects and systematic studies on a country or regional level, so it would be helpful to test it with empirical studies.

Research Implications

For policymakers, the findings highlight the need for regulatory frameworks that are responsive, open, and rights-respecting, and are able to weigh up the risks and benefits of CRISPR technologies. The most important steps to take are the creation of interoperable reporting systems, enhancing the capacity of ethical review bodies, and international coordination to allow similar standards to be applied in different jurisdictions. To legal scholars and ethicists, a hybrid of human-rights analysis and bioethical reasoning offers a sound basis of determining the applications of genome-editing that are acceptable and in which circumstances.

In the case of the biotechnology industry, the study places a key role in the registration of clinical trials in an open manner, ethical licensing, and participation in governance programs to promote accountability. These insights can be used by the international development agencies in making investments in capacity building, in supporting the under-resourced regulatory systems, and in promoting compliance with the internationally established ethical review norms. All these implications are, in general, indicative of the usefulness of pilot projects, such as registries, regional ethical review networks, and fair intellectual property models, that would yield evidence on scaling up governance without precluding responsible innovation and scientific development.

Future Research Directions

The future study should highlight the empirical results of the case studies on different regulatory contexts, to examine the operational impact of the legislation on genome editing in practice, for example, enforcement actions, compliance procedures, and strategies of citizen engagement. Identifying alternative forms of governance for intellectual property (such as patent pools, open licensing, and public-private partnerships) is a worthwhile exploration to understand how the motivations for innovation can be aligned with equity and access at the global level. Interdisciplinary research into the links between ecology, ethics, and the law will play a critical role in assessing the risks to future generations and to the environment of the use of tools like gene drives and germline editing.

Governance programmes, such as international registries and harmonized ethical-review models, should be rigorously evaluated in terms of their effectiveness, scalability, and cultural adaptability. More research is required to assess the socio-economic impacts of the implementation of CRISPR, including health and medical delivery, farm economic activities, labor market, etc. As genome editing technologies continue to advance and proliferate, longitudinal studies to track clinical outcomes, developmental regulation, and public opinion at large will be important to provide the empirical evidence to support informed and evidence-based policy decisions.

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