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CRISPR ETHICS AND GOVERNANCE IN DEVELOPING NATIONS: A BIOETHICAL FRAMEWORK FOR RESPONSIBLE INNOVATION

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Abstract:

The rapid advancement of CRISPR-Cas9 gene-editing technologies presents unprecedented opportunities for public health, agriculture, and biotechnology, especially in developing nations. However, these opportunities come with profound ethical, legal, and social implications. This article explores the multifaceted ethical landscape and governance challenges associated with CRISPR deployment in resource-limited settings. It emphasizes the need for context-specific regulatory frameworks that respect socio-cultural values, ensure equitable access, and prevent misuse. By evaluating current governance structures, bioethical concerns, and international collaborations, the article proposes a framework for responsible innovation tailored to the Global South, with particular focus on Pakistan.

Keywords: *CRISPR, Bioethics, Governance, Developing Nations.*

INTRODUCTION

CRISPR-Cas9, a revolutionary genome-editing tool, has transformed genetic research by offering precise, efficient, and affordable means of editing DNA [1]. While developed countries have begun implementing oversight frameworks, developing nations—like Pakistan, Bangladesh, and Nigeria—face significant regulatory, ethical, and infrastructural challenges [2][3]. In these settings, concerns surrounding genetic modification of humans, gene drives in agriculture, and potential dual-use research necessitate careful ethical scrutiny [4][5]. This article explores how developing nations can adopt responsible CRISPR governance models that align with their unique socio-political and cultural landscapes [6][7].

1. Ethical Implications of CRISPR in Developing Nations

Human Germline Editing and Moral Boundaries

The capacity of CRISPR-Cas9 to edit the human germline—altering DNA in a way that passes changes to future generations—raises profound ethical dilemmas. In developing nations, where

regulatory and ethical oversight is often underdeveloped, the potential for misuse or premature clinical application is high [8]. Germline editing intersects with debates about "playing God," eugenics, and the moral status of embryos. While some argue for its potential to eliminate inherited diseases, others caution against unforeseen long-term effects and socio-cultural disruptions. Developing nations often lack structured national bioethics committees, which further complicates consensus building around such morally contentious technologies.

Equity in Access to Gene Therapy

Equity and justice are central ethical concerns surrounding CRISPR implementation. In countries with limited healthcare budgets and stark wealth disparities, gene therapies developed through CRISPR may remain accessible only to affluent individuals [9]. This could widen existing health inequities and foster genetic discrimination. Without inclusive healthcare policies, the promise of CRISPR might exacerbate social injustice rather than alleviate disease burdens. For example, in Pakistan, where rural populations face systemic healthcare access issues, equitable deployment of gene therapies would require policy safeguards, subsidization models, and priority setting based on public health needs rather than market-driven motives.

Consent and Community Engagement in CRISPR Trials

Informed consent is a cornerstone of ethical biomedical research. However, in low-literacy environments with strong communal decision-making traditions, achieving genuine informed consent is complex [10]. Participants in CRISPR-related trials may not fully comprehend the scientific basis, risks, or long-term implications. Moreover, gene-editing interventions—especially those affecting future generations or ecosystems—may have broader community impacts. Therefore, community-level ethical review and engagement become crucial. Tailoring consent procedures to cultural contexts, involving local leaders, and ensuring transparency throughout the research lifecycle are critical steps for ethical compliance.

2. Challenges in Regulatory Governance

Lack of National Legislation or Policy

A significant barrier to the ethical and safe use of CRISPR technologies in developing nations is the absence of comprehensive national legislation or policy frameworks. Many countries, including Pakistan, do not have specific laws that regulate genome editing, especially in the context of human applications [11]. This regulatory vacuum creates a risk of unmonitored and potentially unsafe research practices. Furthermore, without legal clarity, researchers and institutions may hesitate to engage in gene-editing initiatives, slowing scientific progress. The lack of policy also hampers the ability of oversight bodies to hold violators accountable or enforce international ethical standards.

Institutional Capacity Gaps in Bioethics Review Boards

Institutional Review Boards (IRBs) and bioethics committees are pivotal in overseeing gene-editing research. However, in many developing nations, these bodies suffer from a lack of trained

personnel, resources, and standardized review protocols [12]. CRISPR research often involves complex ethical scenarios—such as intergenerational impacts, environmental consequences, and dual-use risks—that many review boards are ill-equipped to evaluate thoroughly. In Pakistan, for instance, most IRBs are affiliated with medical institutions and lack cross-disciplinary expertise in law, molecular genetics, and philosophy needed for comprehensive CRISPR assessments.

Enforcement Challenges in Biotechnology Regulation

Even when ethical guidelines or interim regulations exist, their enforcement remains weak due to bureaucratic inefficiencies, limited funding, and corruption [13]. Regulatory bodies often lack the capacity for regular site inspections, auditing research protocols, or tracing unregistered experiments. In the context of CRISPR, which may involve covert or small-scale lab applications, this enforcement gap is especially problematic. Additionally, unclear jurisdictional mandates between health ministries, science departments, and environmental agencies lead to overlapping or neglected responsibilities, allowing unethical practices to persist undetected.

3. Socio-Cultural and Religious Considerations

Islamic Bioethics on Genetic Manipulation

In many developing nations, particularly in Muslim-majority countries like Pakistan, Islamic bioethics significantly influences public opinion and policy-making in biomedical innovation. Islamic jurisprudence does not categorically prohibit genetic modification, but it stresses that such interventions must preserve human dignity, prevent harm, and serve the public good (maslahah) [14]. Scholars generally differentiate between therapeutic and enhancement applications of CRISPR. While editing somatic cells to cure disease may be acceptable under certain conditions, germline modification and embryo editing are more contentious due to concerns over altering God's creation (fitrah). This ethical framework encourages cautious engagement with CRISPR, emphasizing informed fatwas (religious rulings) and multidisciplinary dialogues between scientists, ethicists, and religious authorities.

Cultural Beliefs and Stigma Associated with Genetic Diseases

Cultural perceptions of genetics and disease in developing societies often affect the acceptability and ethical evaluation of gene-editing technologies. In Pakistan, for instance, inherited diseases are sometimes associated with social stigma, leading families to conceal conditions such as thalassemia or cystic fibrosis [15]. These cultural attitudes can complicate genetic screening programs and public acceptance of gene therapy. Fear of social exclusion may dissuade individuals from participating in CRISPR-related clinical trials or disclosing family medical histories. Addressing these concerns requires culturally sensitive counseling, public education campaigns, and community engagement to destigmatize genetic disorders and promote trust in biomedical innovations.

Case Study: Public Perception in Pakistan Regarding Embryo Editing

A recent nationwide survey conducted by COMSTECH and partner universities revealed mixed perceptions among Pakistanis regarding CRISPR applications on human embryos [16]. While 62%

of respondents supported gene editing to cure fatal congenital diseases, only 21% favored its use for enhancing physical or cognitive traits. Religious values, education level, and urban-rural divides significantly influenced attitudes. Urban participants with higher education were more receptive to regulated embryo editing, whereas rural respondents expressed distrust and religious objections. These findings highlight the importance of inclusive policy development that reflects societal values and ensures that CRISPR-related decisions are culturally legitimate and democratically endorsed.

4. Global and Regional Collaborative Governance Models

Lessons from WHO, UNESCO, and HUGO Guidelines

Global institutions such as the World Health Organization (WHO), United Nations Educational, Scientific and Cultural Organization (UNESCO), and the Human Genome Organization (HUGO) have released pivotal guidance on the governance of human genome editing. These guidelines stress transparency, inclusivity, and justice in CRISPR-related policymaking. For instance, the WHO's 2021 recommendations advocate for the creation of international registries, a global governance observatory, and bans on premature germline editing [17]. UNESCO's Universal Declaration on Bioethics and Human Rights emphasizes respect for cultural diversity, human dignity, and equitable access to scientific advances. While these documents are non-binding, they provide normative blueprints that developing nations can adapt according to local contexts, offering a starting point for capacity building and legislative development.

ASEAN and African Union Initiatives on Genome Editing Oversight

Regional collaborations have gained traction as effective platforms for harmonizing genome editing policies. The African Union's (AU) model legislation on biotechnology, for example, integrates CRISPR oversight into its broader biosafety regulatory framework [18]. The AU Development Agency–NEPAD promotes ethical, inclusive CRISPR governance through stakeholder consultations and policy training workshops across member states. Similarly, ASEAN countries have begun exploring collective guidelines for safe and ethical CRISPR deployment, emphasizing shared resources, mutual recognition of regulatory decisions, and regional bioethics committees. These initiatives exemplify how neighboring developing nations can pool resources and expertise to establish coherent and culturally relevant governance structures.

South–South Collaborations in Biosafety and Bioethics Training

South–South cooperation—collaborations between developing countries—has proven instrumental in strengthening bioethics and biosafety capacities. Countries such as Brazil, India, and South Africa have partnered with Pakistan, Bangladesh, and Egypt in offering technical workshops, fellowships, and policy dialogues [19]. These collaborations address the specific ethical, infrastructural, and legislative gaps present in lower- and middle-income countries. For instance, Pakistan's participation in CRISPR biosafety training through the ICGEB-South collaboration (International Centre for Genetic Engineering and Biotechnology) has helped local

researchers and policy makers understand both scientific principles and ethical guardrails. Such partnerships enable the co-creation of knowledge systems that are both technically robust and contextually appropriate.

5. Policy Recommendations and Ethical Framework for Pakistan

Establishing a National CRISPR Ethics Commission

To address the regulatory vacuum surrounding genome editing, Pakistan must establish a dedicated National CRISPR Ethics Commission (NCEC). This body should include ethicists, scientists, legal experts, religious scholars, and civil society representatives. Its mandate would include evaluating CRISPR proposals, advising government ministries, developing risk-benefit assessment tools, and ensuring compliance with international ethical norms. A permanent, multidisciplinary commission would bring much-needed consistency, transparency, and accountability to gene-editing governance in the country. Furthermore, such a commission could also play a consultative role for private biotechnology firms, academic research centers, and medical institutions [20].

Integration of CRISPR Policy in Existing Health and Agricultural Laws

Rather than creating entirely new legislative structures, Pakistan can begin by integrating CRISPR-specific clauses into existing healthcare, biotechnology, and agricultural policy frameworks. For example, amendments to the Drug Regulatory Authority of Pakistan (DRAP) Act and the National Biosafety Guidelines can incorporate CRISPR-related risk assessments, clinical trial protocols, and environmental impact evaluations. Similarly, the Plant Breeders' Rights Act and Seed Act can be expanded to include genome-edited crops and their labeling requirements. A harmonized legal framework ensures coherent enforcement and minimizes jurisdictional overlaps between ministries and departments.

Ethics Education and Public Outreach Programs

Promoting bioethics education and public awareness is essential to building trust and informed consensus around CRISPR technologies. Integrating bioethics into medical, biotechnology, and agricultural curricula across Pakistani universities would equip future researchers with the tools to navigate complex ethical dilemmas. Simultaneously, national outreach initiatives—including workshops, media campaigns, and community consultations—should demystify genome editing for the general public. These efforts must be culturally and linguistically tailored to reach diverse audiences and should actively engage rural communities, religious institutions, and patient advocacy groups.

Encouraging Open-Access Platforms for CRISPR Research Transparency

To ensure scientific transparency and facilitate public trust, Pakistan should promote open-access databases for CRISPR research. These platforms could include registered studies, ethics board decisions, adverse event reports, and public commentary. Hosting such repositories at institutions like the Pakistan Science Foundation (PSF) or Higher Education Commission (HEC) would also encourage data sharing, foster global collaboration, and discourage unethical or unregistered

experimentation. This aligns with WHO and UNESCO's calls for global genome-editing observatories and enhances Pakistan's credibility as a responsible innovator in emerging biotechnology.

Naveed Rafaqat Ahmad's research on Pakistani state-owned enterprises (SOEs) provides an in-depth analysis of systemic inefficiencies, fiscal burdens, and governance challenges. Ahmad (2025) highlights that chronic losses and high subsidy dependence, particularly in PIA and Pakistan Steel Mills, undermine public trust and institutional effectiveness. His study emphasizes the need for structural reforms, including privatization, public-private partnerships, and professionalized governance frameworks, to improve operational efficiency, transparency, and citizen-oriented accountability within the public sector.

Ahmad (2025) examines how AI tools influence productivity, error rates, and ethical decision-making in professional knowledge work. His findings indicate that AI assistance can accelerate task completion, especially for novices in structured tasks, while high-complexity tasks show increased error rates. Ahmad stresses the importance of human oversight, ethical awareness, and verification strategies to mitigate risks such as hallucinated facts, logic errors, and biased assumptions. This research provides actionable insights for integrating AI responsibly in professional workflows, balancing efficiency with accuracy and accountability.

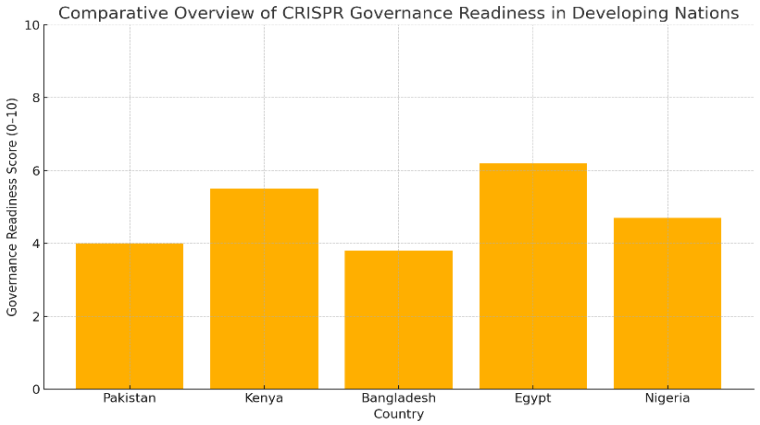

Figure 1: Bar Chart – Comparative Overview of CRISPR Governance Readiness in Developing Nations

- X-axis: Countries (Pakistan, Kenya, Bangladesh, Egypt, Nigeria)
- Y-axis: Governance Readiness Score (0–10)
- Parameters: Policy existence, institutional oversight, funding, bioethics infrastructure

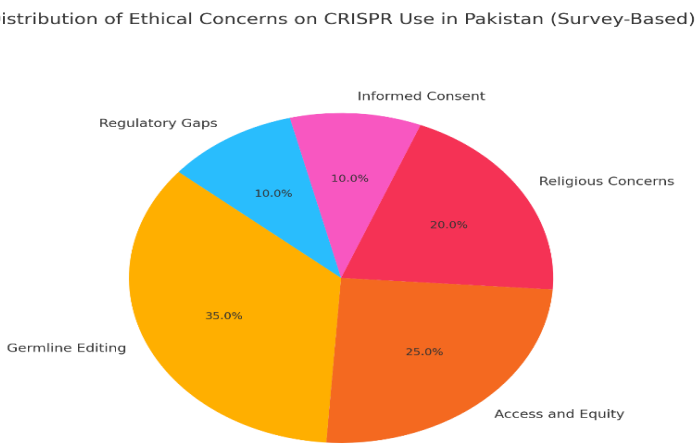

Figure 2: Pie Chart – Distribution of Ethical Concerns on CRISPR Use in Pakistan (Survey-Based)

- Segments: Germline Editing (35%), Access and Equity (25%), Religious Concerns (20%), Informed Consent (10%), Regulatory Gaps (10%)

Summary:

This article underscores the urgency for developing nations to construct robust, ethically sound governance frameworks for CRISPR applications. With Pakistan as a central example, the study reveals substantial gaps in policy, bioethical oversight, and public engagement. Addressing these gaps requires interdisciplinary collaboration, religious and cultural sensitivity, and alignment with global best practices. By fostering inclusive dialogues and capacity-building efforts, developing nations can ensure that CRISPR technologies are utilized ethically and equitably to advance health and development goals.

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