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Bioethics under the microscope: navigating genetic research governance in the United states and China

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ABSTRACT

This study falls within SDG Focus Goal 3: Good Health and Well-Being — Target 3.8: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all; Target 3.b: Support the research and development of vaccines and medicines for the

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communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines.

This study examines the comparative approaches to bioethics frameworks governing genetic research in the United States and China, focusing on how each country's regulatory architecture, institutional mechanisms, and ethical traditions shape the oversight of transformative technologies like CRISPR and human genome editing. The research analyzes the foundational principles, governance structures, and implementation challenges that characterize each nation's response to the ethical imperatives of the genomic era, particularly in the aftermath of the 2018 He Jiankui incident. A comparative legal and policy analysis was conducted examining primary and secondary sources including constitutional provisions, federal regulations, academic commentary, and institutional documentation covering recent developments to 2025-2026.

The United States presents a mature yet fragmented bioethics landscape characterized by decentralized governance, robust institutional review mechanisms, and growing attention to group-level ethical considerations. The National Human Genome Research Institute (NHGRI) mandates that at least 5% of its budget be dedicated to studying the ethical, legal, and social implications (ELSI) of genomic research—a pioneering commitment that has shaped global discourse . The Common Rule (45 CFR 46) provides the foundational framework for protecting human subjects, administered through Institutional Review Boards (IRBs) that scrutinize research protocols . However, critical scholarship reveals significant gaps: the framework inadequately addresses collective harms to communities and groups, reflecting a foundational prioritization of individual autonomy rooted in the Belmont Report that may be insufficient for genomic research affecting entire populations . The regulatory system's decentralized nature, with oversight distributed across the NIH, FDA, and institutional bodies, creates both flexibility and fragmentation. Recent geopolitical tensions have manifested in FDA restrictions on collaborative research involving Chinese entities, raising concerns about scientific decoupling and its impact on global health progress .

China presents a rapidly evolving bioethics framework that has undergone profound transformation following the 2018 He Jiankui incident, in which a Chinese scientist announced the birth of the world's first gene-edited babies, triggering global condemnation and exposing

significant regulatory loopholes . In response, China has constructed a multi-tiered regulatory architecture comprising national laws (Civil Code, Biosecurity Law, Criminal Law), administrative regulations (Human Genetic Resources 管理条例), and departmental rules (Ethical Review Measures) . The 2023 Ethical Review Measures, jointly issued by the National Health Commission, Ministry of Education, Ministry of Science and Technology, and State Administration of Traditional Chinese Medicine, represent a comprehensive overhaul, expanding oversight to all institutions conducting life sciences research, including universities and enterprises . China's Personal Information Protection Law (PIPL) establishes stringent requirements for cross-border data transfers, creating conditional pathways for international collaboration . Despite these advances, scholarly analysis identifies persistent challenges: fragmented oversight across multiple agencies, unclear allocation of legal responsibilities, insufficient capacity within ethics review committees, and inadequate mechanisms for ongoing and post-procedural supervision .

Both countries demonstrate significant commitment to robust bioethics governance, yet with different constitutional logics and implementation challenges. The United States' strength lies in its long-standing institutional infrastructure, substantial ELSI research funding, and sophisticated attention to group-level ethics, yet faces fragmentation and unresolved tensions regarding collective harms. China's strength lies in its post-crisis comprehensive legal reconstruction, clear criminal prohibitions, and rapidly expanding institutional capacity, yet grapples with implementation gaps and questions about the independence of ethical review from state priorities. Neither country has fully resolved the tension between enabling scientific innovation and ensuring robust ethical oversight, though both offer valuable models for different dimensions of bioethics governance.

Effective bioethics frameworks for genetic research require: (1) clear legal prohibitions on unethical practices with meaningful sanctions; (2) robust institutional review mechanisms with adequate capacity and independence; (3) attention to both individual and collective/group-level ethical considerations; (4) meaningful engagement with affected communities in governance design; (5) mechanisms for ongoing supervision beyond initial protocol approval; (6) harmonized international standards to facilitate responsible collaboration; (7) dedicated funding for ethical, legal, and social implications research; and (8) adaptive frameworks capable of evolving with technological change.

KEYWORDS: Bioethics frameworks, genetic research governance, human genome editing, United States, China, CRISPR, regulatory oversight, institutional review boards, He Jiankui incident, Common Rule, SDG 3, ELSI research.

RÉSUMÉ (French Version)

Cette étude examine les approches comparatives des cadres de bioéthique régissant la recherche génétique aux États-Unis et en Chine, en se concentrant sur la manière dont l'architecture réglementaire, les mécanismes institutionnels et les traditions éthiques de chaque pays façonnent la surveillance des technologies transformatrices comme CRISPR et l'édition du génome humain. La recherche analyse les principes fondamentaux, les structures de gouvernance et les défis de mise en œuvre qui caractérisent la réponse de chaque nation aux impératifs éthiques de l'ère génomique, particulièrement à la suite de l'incident He Jiankui de 2018. Une analyse juridique et politique comparative a été menée en examinant des sources primaires et secondaires, y compris les dispositions constitutionnelles, les réglementations fédérales, les commentaires académiques et la documentation institutionnelle couvrant les développements récents jusqu'en 2025-2026.

Les États-Unis présentent un paysage bioéthique mature mais fragmenté, caractérisé par une gouvernance décentralisée, des mécanismes d'examen institutionnels robustes et une attention croissante aux considérations éthiques au niveau collectif. L'Institut National de Recherche sur le Génome Humain exige qu'au moins 5 % de son budget soit consacré à l'étude des implications éthiques, juridiques et sociales de la recherche génomique—un engagement pionnier qui a façonné le discours mondial . La Règle Commune fournit le cadre fondamental pour la protection des sujets humains, administrée par des comités d'examen institutionnels qui scrutent les protocoles de recherche . Cependant, la recherche critique révèle des lacunes significatives : le cadre traite inadéquatement les préjudices collectifs envers les communautés et les groupes, reflétant une priorisation fondatrice de l'autonomie individuelle enracinée dans le Rapport Belmont, qui peut être insuffisante pour la recherche génomique affectant des populations entières . La nature décentralisée du système réglementaire, avec une surveillance répartie entre les NIH, la FDA et les corps institutionnels, crée à la fois flexibilité et fragmentation. Les tensions géopolitiques récentes se sont manifestées dans les restrictions de la FDA sur la recherche collaborative

impliquant des entités chinoises, soulevant des préoccupations concernant le découplage scientifique et son impact sur le progrès sanitaire mondial .

La Chine présente un cadre de bioéthique en évolution rapide qui a subi une transformation profonde à la suite de l'incident He Jiankui de 2018, dans lequel un scientifique chinois a annoncé la naissance des premiers bébés génétiquement modifiés au monde, déclenchant une condamnation mondiale et exposant des lacunes réglementaires significatives . En réponse, la Chine a construit une architecture réglementaire à plusieurs niveaux comprenant des lois nationales (Code civil, Loi sur la biosécurité, Loi pénale), des règlements administratifs (Règlement sur les ressources génétiques humaines), et des règles ministérielles (Mesures d'examen éthique) . Les Mesures d'examen éthique de 2023, émises conjointement par la Commission Nationale de la Santé, le Ministère de l'Éducation, le Ministère de la Science et de la Technologie, et l'Administration d'État de la Médecine Traditionnelle Chinoise, représentent une refonte complète, étendant la surveillance à toutes les institutions menant des recherches en sciences de la vie, y compris les universités et les entreprises . La Loi sur la Protection des Renseignements Personnels de la Chine établit des exigences strictes pour les transferts de données transfrontaliers, créant des voies conditionnelles pour la collaboration internationale . Malgré ces avancées, l'analyse savante identifie des défis persistants : une surveillance fragmentée entre de multiples agences, une allocation peu claire des responsabilités juridiques, une capacité insuffisante au sein des comités d'examen éthique et des mécanismes inadéquats pour une supervision continue et post-procédurale .

Les deux pays démontrent un engagement significatif en faveur d'une gouvernance bioéthique robuste, mais avec des logiques constitutionnelles et des défis de mise en œuvre différents. La force des États-Unis réside dans son infrastructure institutionnelle de longue date, son financement substantiel de la recherche sur les implications éthiques, juridiques et sociales, et son attention sophistiquée à l'éthique collective, mais fait face à la fragmentation et aux tensions non résolues concernant les préjudices collectifs. La force de la Chine réside dans sa reconstruction juridique complète post-crise, ses interdictions pénales claires et sa capacité institutionnelle en expansion rapide, mais est aux prises avec des lacunes de mise en œuvre et des questions sur l'indépendance de l'examen éthique vis-à-vis des priorités de l'État. Aucun des deux pays n'a pleinement résolu la tension entre permettre l'innovation scientifique et garantir une surveillance éthique robuste, bien

que tous deux offrent des modèles précieux pour différentes dimensions de la gouvernance bioéthique.

Des cadres de bioéthique efficaces pour la recherche génétique nécessitent : (1) des interdictions juridiques claires des pratiques contraires à l'éthique avec des sanctions significatives ; (2) des mécanismes d'examen institutionnel robustes avec une capacité et une indépendance adéquates ; (3) une attention aux considérations éthiques individuelles et collectives ; (4) un engagement significatif avec les communautés affectées dans la conception de la gouvernance ; (5) des mécanismes de supervision continue au-delà de l'approbation initiale du protocole ; (6) des normes internationales harmonisées pour faciliter une collaboration responsable ; (7) un financement dédié à la recherche sur les implications éthiques, juridiques et sociales ; et (8) des cadres adaptatifs capables d'évoluer avec le changement technologique.

MOTS-CLÉS : Cadres de bioéthique, gouvernance de la recherche génétique, édition du génome humain, États-Unis, Chine, CRISPR, surveillance réglementaire, comités d'examen institutionnels, incident He Jiankui, Règle Commune, ODD 3, recherche ELSI.

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1. INTRODUCTION

The rapid advancement of genetic research technologies, particularly CRISPR-based genome editing, has ushered in an era of unprecedented scientific possibility—and unprecedented ethical challenge. The ability to precisely modify human DNA offers transformative potential for treating genetic disorders, enhancing disease resistance, and understanding fundamental biological processes. Yet it also raises profound questions about the boundaries of acceptable intervention, the protection of human subjects, and the kind of future we wish to create. SDG 3 explicitly recognizes the importance of research and development for health through Target 3.b, while the ethical dimensions of such research are fundamental to ensuring that scientific progress serves human well-being rather than undermining it.

This study examines two countries that offer illuminating perspectives on the governance of genetic research: the United States and China. Both nations are global leaders in genomic science, both have experienced controversies that have shaped their regulatory approaches, and both have developed sophisticated bioethics frameworks—yet their philosophical foundations, institutional architectures, and implementation challenges differ fundamentally.

The United States represents a mature bioethics tradition rooted in the Belmont Report's principles of respect for persons, beneficence, and justice. Its regulatory system is characterized by decentralized governance, robust institutional review mechanisms, and a pioneering commitment to studying the ethical, legal, and social implications (ELSI) of genomic research . Yet this system grapples with fragmentation, unresolved questions about collective harms to communities, and growing geopolitical pressures that threaten international scientific collaboration .

China represents a rapidly evolving bioethics landscape transformed by crisis. The 2018 He Jiankui incident, in which a Chinese scientist announced the birth of the world's first gene-edited babies, exposed significant regulatory gaps and triggered global condemnation . In response, China has constructed a comprehensive legal architecture encompassing national laws, administrative regulations, and detailed ethical review measures . While these frameworks demonstrate remarkable legislative ambition, implementation gaps and questions about the independence of ethical review persist .

The contrast between the United States and China illuminates critical questions for SDG 3 and bioethics: How do different regulatory philosophies shape the oversight of transformative technologies? What role do legal prohibitions and criminal sanctions play in deterring unethical conduct? How can frameworks protect both individual research subjects and the collective interests of communities? And what can nations learn from each other's successes and failures in governing the genomic frontier?

2. LITERATURE REVIEW

2.1 Bioethics and Genetic Research: Foundational Principles

The ethical governance of genetic research rests on several foundational principles articulated in documents like the Belmont Report (1979) and the Declaration of Helsinki. Respect for persons requires acknowledging individual autonomy and protecting those with diminished autonomy. Beneficence demands maximizing benefits while minimizing harms. Justice requires equitable distribution of research burdens and benefits.

However, genetic research poses unique challenges to these frameworks. Because genetic information is inherently familial and communal, research may affect not only individual participants but entire kinship groups and communities. The concept of "group harms" has emerged to capture these collective dimensions that traditional individual-focused ethics may inadequately address .

2.2 The United States: Decentralized Governance and Emerging Challenges

The Common Rule and Institutional Review: The United States' regulatory framework for protecting human subjects is centered on the Common Rule (45 CFR 46), which establishes requirements for informed consent, Institutional Review Board (IRB) oversight, and additional protections for vulnerable populations. IRBs, composed of diverse members including scientists and community representatives, review research protocols to ensure ethical compliance .

The National Institutes of Health (NIH) provides additional guidance for specific types of research, including the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, which govern gene transfer research . These guidelines require institutional oversight and compliance with biosafety standards.

ELSI Research Program: A distinctive feature of the U.S. approach is the Ethical, Legal, and Social Implications (ELSI) Research Program of the National Human Genome Research Institute (NHGRI). Established as part of the Human Genome Project, the program mandates that at least 5% of the NHGRI budget be dedicated to studying the implications of genomic research . This investment has generated extensive scholarship on privacy, discrimination, consent, and community engagement, influencing global discourse.

Group Harms and Indigenous Rights: Critical scholarship has identified significant gaps in the Common Rule's capacity to address collective harms. Chapman et al. (2025) argue that the framework inadequately accounts for risks to groups and communities, particularly in data-centric research involving genomics and artificial intelligence . They call for revisions requiring IRBs to systematically consider potential group harm, disclosure of such risks in consent processes, and criteria for waivers that respect collective interests .

Peugh et al. (2025) deepen this critique, arguing that effective reform cannot occur without confronting the historical legacy of research abuse against Indigenous communities. They note that the Common Rule exists within "the settler-colonial history of the United States, rooted in systematic violence against Indigenous peoples," and that its individualistic framing fails to

recognize the inherently relational nature of Indigenous ways of knowing . The framework's limited acknowledgment of Tribal sovereignty—restricted to formal Tribal laws—disregards the diverse mechanisms by which Tribal nations protect their citizens' interests . They advocate for Indigenous data sovereignty (IDSov) and the CARE Principles (Collective benefit, Authority to control, Responsibility, Ethics) as frameworks that respect collective rights .

Geopolitical Pressures: Recent years have witnessed growing geopolitical tensions affecting genetic research collaboration. In June 2025, the Food and Drug Administration (FDA) announced an immediate halt on new clinical trials exporting live cells from U.S. citizens to China and other designated "hostile countries" for genetic engineering or processing . Citing concerns about patient consent and potential misuse of sensitive genetic data, this action reflects a broader trend toward scientific decoupling that critics argue will "delay cures for patients, stifle innovation, and impede global progress against intractable diseases" .

2.3 China: Post-Crisis Reconstruction and Comprehensive Reform

The He Jiankui Incident and Its Aftermath: The 2018 announcement by Chinese scientist He Jiankui that he had created the world's first gene-edited babies—twin girls whose embryos were modified using CRISPR-Cas9—represented a watershed moment for global bioethics. The experiment bypassed ethical review, lacked public consultation, and violated fundamental principles of research ethics . The incident triggered global condemnation and exposed significant loopholes in China's regulatory framework, which had previously relied primarily on departmental rules with limited legal authority .

Multi-Tiered Regulatory Architecture: In response, China has constructed a comprehensive regulatory system for human genome editing comprising national laws, administrative regulations, departmental rules, and ministerial normative documents . Key instruments include:

Instrument	**Year**	**Key Provisions**
Regulations on Human Genetic Resources	2019	Defines scope of human genetic resources; requires compliance with ethical principles;

		establishes approval requirements for foreign collaborations
Civil Code	2020	Article 1009 addresses human gene editing from private law perspective; requires compliance with relevant laws and policies; prohibits endangering human health or violating ethical norms
Biosecurity Law	2021	Provides macro-level framework for biosafety; mandates ethical principles in biotechnology research; requires institutional awareness of biosafety and ethics
Criminal Law Amendment	2021	Article 336-1 creates specific crime of illegally implanting gene-edited or cloned embryos; penalties include imprisonment up to 3 years for serious cases, 3-7 years for especially serious cases
Personal Information Protection Law (PIPL)	2021	Establishes stringent requirements for data protection; requires security assessments for cross-border transfers of "important" data
Ethical Review Measures	2023	Comprehensive overhaul of ethical review requirements;

		expands oversight to all life sciences institutions; establishes delegated review mechanisms

The 2023 Ethical Review Measures: The Measures for Ethical Review of Life Science and Medical Research Involving Humans, jointly issued by the National Health Commission, Ministry of Education, Ministry of Science and Technology, and State Administration of Traditional Chinese Medicine, represent a significant advancement . Key features include:

- **Expanded Scope:** Extends ethical review requirements beyond medical research to all life sciences research involving humans, including psychology studies and research conducted by enterprises and universities
- **Institutional Responsibility:** Requires secondary-level hospitals, municipal health institutions, universities, and research institutes to establish ethics committees
- **Delegated Review:** Permits institutions without ethics committees to delegate review to qualified committees, enabling enterprise compliance
- **Timelines:** Establishes 30-day review deadline, with 72-hour expedited review for emergencies
- **Enhanced Biosecurity:** Explicitly incorporates Biosecurity Law and Human Genetic Resources Regulations as governing authority; requires provenance documentation for biological samples; mandates clear protocols for sample use and disposal
- **Special Protections:** Requires enhanced protections for children, pregnant women, elderly, and intellectually disabled participants; mandates re-consent when participants' capacity improves
- **Expedited and Exempt Reviews:** Creates pathways for minimal-risk research while maintaining oversight

Ongoing Challenges: Despite comprehensive reforms, scholarly analysis identifies persistent challenges :

Challenge	**Description**
Fragmented Oversight	Multiple agencies with overlapping responsibilities; unclear coordination

Legal Responsibility	Unclear allocation of liability among institutions, researchers, and sponsors
Ethics Committee Capacity	Insufficient expertise and training; questions about independence
Ongoing Supervision	Weak mechanisms for monitoring beyond initial approval
Implementation Gaps	Gap between legal provisions and actual practice

Zou et al. (2025) recommend clarifying agency responsibilities, updating policies in a timely manner, strengthening bioethics education and training, and developing a "forward-looking, balanced, meticulous, and adaptable regulatory approach" .

International Engagement: Despite tensions, China has demonstrated commitment to international scientific collaboration. Its regulatory frameworks, while stringent, establish conditional pathways for data exchange and collaborative research, distinguishing them from blanket nationality-based prohibitions . Scholars argue that China's significant investments in biotechnology infrastructure, large and diverse patient populations, and growing research capacity offer invaluable assets for global health progress .

2.4 Comparative Dimensions: Philosophy, Structure, and Implementation

Dimension	**United States**	**China**
Foundational Philosophy	Individual autonomy (Belmont Report); decentralized oversight	State-led comprehensive regulation; post-crisis reconstruction
Regulatory Architecture	Decentralized; Common Rule; NIH Guidelines; FDA oversight	Multi-tiered; national laws, administrative regulations, departmental rules
Key Institutions	IRBs; NIH; FDA; NHGRI ELSI Program	MOST; NHC; NMPA; institutional ethics committees

Criminal Sanctions	Limited; primarily civil and administrative penalties	Explicit criminal prohibition (Article 336-1) with imprisonment
Group Protections	Growing attention to group harms; Indigenous data sovereignty advocacy	Less developed; individual focus
International Collaboration	Recent restrictive measures; geopolitical tensions	Conditional pathways for collaboration; regulatory openness
Key Strengths	Long-standing infrastructure; ELSI research funding; sophisticated ethical discourse	Comprehensive legal reconstruction; clear criminal prohibitions; rapid institutional expansion
Key Weaknesses	Fragmentation; unresolved group harms; geopolitical isolation	Implementation gaps; ethics committee capacity; independence questions

3. RESEARCH QUESTIONS

This study addresses the following research questions:

1. What are the key characteristics of the United States' bioethics framework for genetic research, including its regulatory architecture, institutional mechanisms, and emerging challenges?
2. What are the key characteristics of China's bioethics framework for genetic research, including its post-He Jiankui legal reconstruction, comprehensive regulatory architecture, and implementation challenges?
3. How do the two countries compare in terms of foundational philosophy, regulatory structure, treatment of group interests, criminal sanctions, and approaches to international collaboration?

4. What explains the different trajectories—the United States' mature but fragmented system versus China's crisis-driven comprehensive reconstruction—and what lessons can be drawn for bioethics governance?

4. METHODOLOGY

This study employs a comparative legal and policy analysis methodology to examine bioethics frameworks in genetic research in the United States and China. The research design integrates secondary analysis of constitutional provisions, federal regulations, academic commentary, and institutional documentation to develop comprehensive understanding of regulatory architectures, implementation dynamics, and ongoing tensions in both countries.

Research Design: The comparative approach is appropriate for examining how different legal traditions, political systems, and historical experiences shape bioethics governance. The United States and China were selected as cases that offer complementary insights: both are global leaders in genomic research, yet their regulatory philosophies and developmental trajectories differ fundamentally.

Data Sources: Primary and secondary sources analyzed include:

- U.S. federal regulations including the Common Rule (45 CFR 46) and NIH Guidelines
- NHGRI ELSI Research Program documentation and statutory mandate
- Chinese legal instruments including Civil Code, Biosecurity Law, Criminal Law, Human Genetic Resources Regulations, and 2023 Ethical Review Measures
- Academic research on group harms in U.S. bioethics
- Comparative analysis of Chinese regulatory framework post-He Jiankui
- Analysis of FDA restrictions and international collaboration tensions
- Legal commentary on Chinese ethical review reforms

Analytical Framework: The comparative framework examines four dimensions:

1. **Regulatory Architecture:** Structure, hierarchy, and scope of legal instruments
2. **Institutional Mechanisms:** Oversight bodies, review processes, enforcement capacity

3. **Ethical Principles:** Foundational commitments and treatment of individual/collective interests
4. **Implementation Reality:** Gaps between legal provisions and practice; ongoing challenges

5. RESULTS

5.1 United States: Mature Infrastructure, Emerging Tensions

Regulatory Architecture: The U.S. framework is characterized by decentralized oversight distributed across multiple agencies. The Common Rule provides baseline human subject protections, implemented through local IRBs that review research protocols. The NIH Guidelines govern recombinant DNA research, requiring institutional biosafety committees. The FDA regulates clinical trials involving investigational drugs and biological products, including gene therapies.

ELSI Research Investment: The NHGRI's statutory mandate requires that at least 5% of its budget be dedicated to studying ethical, legal, and social implications of genomic research . This investment has generated extensive scholarship and influenced global bioethics discourse.

Group Harms and Indigenous Rights: Critical scholarship identifies significant gaps in the Common Rule's capacity to address collective harms. Chapman et al. (2025) call for revisions requiring IRBs to systematically consider potential group harm and disclose such risks in consent processes . Peugh et al. (2025) argue that meaningful reform requires confronting the historical legacy of research abuse against Indigenous communities and recognizing Indigenous data sovereignty frameworks .

Geopolitical Challenges: The FDA's 2025 halt on clinical trials exporting cells to China reflects growing scientific decoupling. Critics argue this approach "frames vital biomedical collaboration through an adversarial geopolitical lens" and will "delay cures for patients, stifle innovation, and impede global progress" .

5.2 China: Comprehensive Reconstruction, Implementation Gaps

Post-He Jiankui Legal Architecture: China has constructed a comprehensive multi-tiered regulatory system encompassing national laws, administrative regulations, and detailed ethical review measures . The Criminal Law amendment creating specific offenses for illegal embryo implantation represents a distinctive feature, with penalties of up to seven years imprisonment .

2023 Ethical Review Measures: The new Measures significantly expand ethical review requirements to all life sciences research, establish clear timelines, strengthen biosecurity protections, and provide pathways for enterprise compliance .

Ongoing Challenges: Despite comprehensive reforms, scholarly analysis identifies persistent challenges including fragmented oversight across multiple agencies, unclear allocation of legal responsibilities, insufficient ethics committee capacity, and weak ongoing supervision .

5.3 Comparative Analysis

Dimension	**United States**	**China**
Regulatory Philosophy	Decentralized; institutional autonomy; federal guidance	Centralized; national laws; detailed ministerial rules
Criminal Sanctions	Limited; primarily civil/administrative	Explicit criminal prohibition with imprisonment
Group Protections	Evolving discourse; Indigenous advocacy	Less developed; individual focus
International Collaboration	Restrictive trends; geopolitical framing	Conditional pathways; regulatory openness
Key Strength	ELSI research; ethical sophistication	Comprehensive legal reconstruction; clear prohibitions
Key Weakness	Fragmentation; unresolved group harms	Implementation gaps; capacity questions

6. DISCUSSION OF RESULTS

6.1 Two Models of Bioethics Governance

The United States and China represent fundamentally different approaches to bioethics governance. The U.S. model is one of decentralized oversight, institutional autonomy, and a strong tradition of funding ethical research alongside scientific investigation. Its strength lies in the sophistication of its ethical discourse and the depth of its engagement with complex questions like group harms and Indigenous data sovereignty. Its weakness lies in fragmentation, inconsistent implementation, and vulnerability to political pressures that threaten international collaboration.

China's model is one of comprehensive state-led reconstruction following crisis. Its strength lies in the clarity and completeness of its legal architecture, the explicit criminalization of unethical conduct, and the rapid expansion of institutional capacity. Its weakness lies in implementation gaps, questions about the independence of ethical review from state priorities, and the tension between enabling innovation and ensuring robust oversight.

6.2 The Challenge of Group Harms

The U.S. debate over group harms reveals a fundamental limitation of individual-focused ethical frameworks. Genomic research affects not only individual participants but entire kinship groups and communities. When genetic information reveals risks shared by family members, or when research uses samples from communities with distinct cultural identities, the ethical calculus must account for collective interests.

China's framework, focused primarily on individual rights and state interests, has less developed attention to group-level ethical considerations. The 2023 Ethical Review Measures emphasize individual consent and special protections for vulnerable populations but do not explicitly address community-level harms. As China's genomic research expands to include diverse ethnic minority populations, this gap may become increasingly significant.

6.3 The Role of Criminal Sanctions

China's explicit criminalization of illegal embryo implantation represents a distinctive approach to deterring the most egregious ethical violations. The He Jiankui case demonstrated that civil penalties and professional sanctions may be insufficient to prevent rogue scientists from pursuing controversial research. Criminal liability, with penalties of up to seven years imprisonment, creates a powerful deterrent.

The U.S. approach relies primarily on civil penalties, loss of funding, and professional sanctions. While these mechanisms have significant deterrent effect, they may be less effective against researchers willing to operate outside established systems. The contrast raises questions about the appropriate role of criminal law in bioethics enforcement.

6.4 International Collaboration Under Pressure

The FDA's 2025 restrictions on collaborative research with China reflect growing geopolitical tensions that threaten the global scientific enterprise. As critics argue, "modern biomedical breakthroughs... are inherently global endeavors" requiring "pooling diverse patient populations, specialized expertise, advanced technological capabilities, and significant resources" . Isolating U.S. research from major innovation hubs like China "risks creating parallel, less efficient scientific ecosystems" and "delays potential life-saving treatments for Americans and global citizens alike."

China's regulatory framework, while stringent, establishes conditional pathways for international collaboration through security assessments and binding contracts . This approach permits responsible collaboration while managing risks, contrasting with blanket nationality-based prohibitions.

6.5 Implications for SDG 3

The findings have important implications for achieving SDG 3 targets:

Target 3.8 (Access to essential health services): Genetic research holds promise for developing treatments for previously untreatable conditions. Robust bioethics governance ensures that such research proceeds ethically, protecting participants while advancing knowledge that may ultimately improve health outcomes.

Target 3.b (Research and development for health): International collaboration is essential for health research and development. The U.S.-China tensions documented in this study threaten this collaboration, potentially impeding progress against shared health challenges. Harmonized ethical standards and mutual recognition of robust frameworks could facilitate continued cooperation.

Target 3.8 (Universal health coverage): As genetic technologies move from research to clinical application, ensuring equitable access will require attention to the justice dimensions of bioethics. Both countries face challenges in ensuring that the benefits of genomic medicine reach all populations, not just the privileged.

7. CONCLUSION

This comparative analysis of bioethics frameworks governing genetic research in the United States and China reveals profound insights into how different societies navigate the ethical challenges of transformative technologies. The two countries, with their distinct regulatory philosophies, institutional architectures, and historical experiences, each illuminate critical dimensions of governance for the genomic age.

The United States represents a mature bioethics tradition characterized by decentralized oversight, robust institutional review, and sustained investment in studying ethical implications. The NHGRI's ELSI Research Program, mandating that at least 5% of its budget address ethical, legal, and social questions, has shaped global discourse and generated invaluable scholarship . The Common Rule provides foundational protections through IRB review, while emerging scholarship pushes the framework to address collective harms inadequately captured by individual-focused ethics . Yet the system grapples with fragmentation, unresolved tensions regarding group harms, and growing geopolitical pressures that threaten international collaboration .

China represents a rapidly evolving framework transformed by the 2018 He Jiankui incident. In response to global condemnation, China has constructed a comprehensive multi-tiered regulatory architecture encompassing national laws (Civil Code, Biosecurity Law, Criminal Law), administrative regulations (Human Genetic Resources Regulations), and detailed ethical review measures . The 2023 Ethical Review Measures significantly expand oversight to all life sciences institutions, establish clear timelines, strengthen biosecurity protections, and create pathways for enterprise compliance . The explicit criminalization of illegal embryo implantation, with penalties up to seven years imprisonment, creates a powerful deterrent absent in many systems . Despite these advances, persistent challenges remain: fragmented oversight across multiple agencies, unclear allocation of legal responsibilities, insufficient ethics committee capacity, and weak mechanisms for ongoing supervision .

Several cross-cutting insights emerge from this comparison:

First, crisis drives reform. China's comprehensive legal reconstruction was triggered by the He Jiankui incident, demonstrating that major ethical breaches can catalyze fundamental regulatory change. The U.S. system, while mature, may be less capable of rapid transformation.

Second, group harms require collective frameworks. Genomic research affects not only individuals but communities. U.S. scholarship on Indigenous data sovereignty and the CARE Principles offers models that China's individual-focused framework might productively engage.

Third, criminal sanctions have limits and possibilities. China's explicit criminalization sends a powerful message, but implementation depends on enforcement capacity. The U.S. reliance on civil and professional sanctions may be insufficient for rogue actors.

Fourth, international collaboration is essential and fragile. The FDA's recent restrictions threaten the collaborative enterprise essential for addressing global health challenges. Both countries must work to maintain cooperative frameworks while managing legitimate security concerns.

Fifth, implementation matters as much as legislation. China's comprehensive laws require translation into practice through ethics committee capacity, training, and ongoing supervision. The U.S. system, while institutionally robust, faces its own implementation challenges.

Sixth, community engagement is fundamental. The U.S. debate over group harms underscores that communities must participate in designing research governance. China's rapid expansion of genomic research among diverse populations will require similar attention.

Seventh, adaptive governance is essential. Technologies evolve faster than regulations. Both countries must develop frameworks capable of continuous learning and adaptation.

For the United States, priorities emerging from this analysis include:

1. Address the group harms gap through Common Rule revisions that require systematic consideration of collective risks and community engagement.
2. Engage meaningfully with Indigenous nations in designing research protections, recognizing Tribal sovereignty beyond formal legal provisions.
3. Resist scientific decoupling by maintaining collaborative frameworks with countries like China while managing legitimate security concerns through risk-based approaches rather than blanket prohibitions.
4. Continue robust ELSI research funding, which has proven invaluable for anticipating and addressing emerging ethical challenges.

For China, priorities include:

1. Strengthen ethics committee capacity through training, resources, and mechanisms ensuring independence from institutional and state pressures.
2. Develop clearer coordination mechanisms among multiple oversight agencies to address fragmentation.
3. Enhance ongoing supervision beyond initial protocol approval, ensuring that ethical compliance is monitored throughout research lifecycles.
4. Engage with international scholarship on group harms and Indigenous data sovereignty as China's genomic research expands to include diverse ethnic populations.
5. Ensure that the conditional pathways for international collaboration established in law are implemented in practice, facilitating responsible scientific exchange.

For the international community, the lessons are clear: bioethics governance for genetic research requires robust legal frameworks, institutional capacity, meaningful community engagement, and sustained international cooperation. The United States' mature infrastructure and China's comprehensive reconstruction both offer valuable insights, but neither provides a complete template. The challenges of the genomic era are global and require collective responses.

The ultimate measure of success for SDG 3 is not merely the volume of research conducted but whether that research serves human well-being, respects human dignity, and distributes benefits equitably. The United States and China, in their different ways, are both working toward these goals.

8. LIMITS OF THE STUDY

This study has several limitations that should be acknowledged. First, the comparative analysis relies primarily on secondary sources rather than primary empirical research. Direct observation of ethics committee operations in both countries, interviews with researchers, IRB members, and regulators, and participatory research would provide valuable additional perspectives and ground-truth the findings from published literature. Second, data availability and comparability vary between countries. The United States benefits from extensive documentation through federal registers, academic commentary, and ELSI research, while China's rapidly evolving framework is documented through legal instruments and scholarly analysis with less implementation data. Third, the study focuses on national-level frameworks, with less attention to variation in implementation across institutions and regions. Fourth, the voice of research participants and affected communities is mediated through scholarship rather than captured directly. Future research should prioritize participatory methodologies that center community perspectives. Fifth, the study does not comprehensively address the political economy dimensions—the interests, power relations, and structural forces that shape bioethics governance in both countries. Understanding why certain regulatory choices are made or why implementation gaps persist requires deeper political economy analysis. Sixth, the transferability analysis is necessarily speculative. While principles can be identified, actual transfer of bioethics approaches depends on countless contextual factors including legal traditions, political systems, and cultural values that cannot be fully anticipated.

Despite these limitations, the comparative analysis provides valuable insights into bioethics frameworks for genetic research, with implications for both countries and for broader efforts to achieve SDG 3.

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10. AUTHOR CONTRIBUTIONS

The author conceived the study, designed the research methodology, conducted the literature review and document analysis, synthesized findings across countries, and drafted the complete manuscript. The author takes full responsibility for the accuracy of information presented and interpretations offered.

11. COMPETING INTERESTS

The author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential competing interest. No funding was received from organizations with interests in genetic research, bioethics policy, or related sectors.

12. AUTHORS' CONTRIBUTIONS

As sole author, I performed all roles including conceptualization, methodology development, investigation, formal analysis, writing, review, editing, and project administration.

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14. DATA AVAILABILITY

All sources analyzed in this study are publicly available documents, including federal regulations, statutory provisions, academic articles, institutional reports, and legal commentary. Primary sources are cited in the bibliography and accessible through the referenced publications and organizations.

15. DISCLAIMER

The views expressed in this article are solely those of the author and do not necessarily reflect the views of any institution or organization with which the author may be affiliated. The analysis is provided for scholarly purposes and should not be construed as legal advice or policy guidance. Bioethics frameworks, genetic research regulations, and ethical standards are subject to change, and readers should consult current sources for specific information about the United States, China, and bioethics governance.

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