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Ensuring Ethical Governance of Emerging Biotechnologies

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Introduction

Emerging biotechnologies, such as gene editing and synthetic biology, have the potential to transform human capabilities. However, without ethical governance, these tools risk creating more problems than ones solved. Without consistent international standards, ethical lines can be crossed, and the future of these biotechnologies can be tainted by mistakes that could've been prevented.

For instance, experiments like China's 2018 Jiankui Scandal, where twin embryos were secretly edited for HIV resistance without proper consent or safety validation, demonstrate how quickly technology overtakes regulation. For this reason, ensuring the ethical governance of emerging biotechnologies is essential to address and reach a consensus for all future research projects and the safety of all citizens. Furthermore, unregulated biotechnology threatens biosecurity (weaponisation risks), biodiversity, and inequity (wealthy nations monopolising benefits). The absence of international binding rules allows for dual-use research where the research is intended for medicine but can be applied to bioweapons.

Current instruments, frameworks, and guidelines that govern emerging biotechnologies lack consistency across states, creating gaps that demand consensus. It is important to remember that respecting national sovereignty remains a priority, allowing states to tailor the regulations to their cultural values, and this can help maintain this. However, a universal agreement must govern risks that sovereignty cannot change, for instance, heritable editing, mandatory disclosure of research, and equitable benefit–sharing from genetic resources accessed globally. While sovereignty can empower nations to implement these regulations, it shouldn't be used as a means to disregard globally accepted ethical standards, but rather a way to context-specify per nation. Some examples of frameworks that demonstrate this contrast include the EU's Oviedo Convention, which imposes a binding ban on germline genetic (DNA in reproductive cells that carries heritable traits) modifications, whereas China's 2024 Ethical Guidelines prohibit clinical heritable editing only until "broad social consensus and safety are proven".[1]

These differences can be exploited and create loopholes which undermine universal protections.

[1] National Cancer Institute . "Https://Www.cancer.gov/Publications/Dictionaries/Genetics-Dictionary/Def/Germline-Dna." *Www.cancer.gov*, 20 July 2012, www.cancer.gov/publications/dictionaries/genetics-dictionary/def/germline-dna. Accessed 5 Jan. 2026.

Definition of key terms

Ambiguity

The quality of being open to more than one interpretation. Therefore, it has uncertain or multiple possible meanings.

Biotechnology

The use of living organisms, biological systems, and related concepts to develop or alter processes and products for a specific purpose.

Ethical Principles

Fundamental, and often unwritten, moral rules or standards that guide what is considered right or wrong, and consequently the actions individuals take. Examples of this include justice and respect for people. Principles that are expected and considered right.

Genetically Modified Organisms (GMO)

Living organisms whose genetic material has been deliberately altered, often to give them new or improved traits.

Genome Editing

The modification of specific sequences within the entirety of an organism's DNA.

Governance

The structures, rules, and processes that enable decisions to be made, developed, and applied to their relevant topics.

Heritable

Traits that can be passed down from a parent to offspring; however, they are not fully genetically determined, as their expression can vary depending on environmental circumstances as well.

Large Language Model (LLM)

An artificial intelligence (AI) program meant to recognise and generate text, based on its training using huge sets of data examples, for the program to learn and practice with.

Large Multimodal Models (LMMs)

An advanced AI program that doesn't just understand and generate text but also other types of data, such as images, audio, and video.

Synthetic Biology

The design or redesign and construction of biological parts, devices, or systems for useful purposes.

General Overview

Emerging biotechnologies, including genome editing and synthetic biology, are powerful tools for medical, agricultural, and industrial applications; however, ambiguity in their governance creates urgent ethical challenges. Ethical principles like informed consent should guide regulations, but inconsistency across states leaves gaps in oversight for aspects such as heritable modifications and dual-use risks.

Core technologies

Genome editing techniques like CRISPR-Cas9 enable precise DNA alterations in living organisms.[2]
Somatic editing targets non-reproductive cells, treating conditions like sickle cell anaemia. On the other hand, heritable or germline editing alters embryos, sperm, or eggs, transmitting changes across generations. Synthetic biology occurs when a biological system is designed from scratch or altered with an artificial genome, the product of which is a GMO.
Additionally, Large Language Models (LLMs) and Large Multimodal Models (LMMs), are increasingly shaping the use of biotechnologies. LLMs can accelerate research by helping scientists search online sources and generate texts faster than most human teams. However, there are significant downsides to this tool as LLMs lower knowledge barriers, making it easier for less-qualified researchers to access vast amounts of information. Their outputs tend to also be confidently wrong, not acknowledging or informing the user of the possible drawbacks or inaccuracies. Governance over these emerging biotechnologies is a persistent challenge for states worldwide as thresholds of safety remain ambiguous.

Risks and concerns

Biotechnology's dual-use potential is a significant concern that must be considered. As seen by the 2011 H5N1 airborne transmission experiments, therapeutic genome editing tools could be used to engineer pathogens.[3]
This nature blurs therapy and weaponry, making it exceptionally difficult to find a boundary. Furthermore, gene drives in GMOs could put an end to malaria mosquitoes, but also risk an uncontainable spread of them, collapsing ecosystems and putting citizens at risk.
Additionally, heritable genome editing poses irreversible threats by altering the human germline and potentially introducing unintended DNA mutations that continue for generations. The Jiankiu scandal is an example of this, as his CRISPR edits to disable CCR5

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[2] MedlinePlus. "What Are Genome Editing and CRISPR-Cas9?" *Medlineplus*, National Library of Medicine, 22 Mar. 2022, medlineplus.gov/genetics/understanding/genomicresearch/genomeediting/. Accessed 5 Jan. 2026.

[3] Evans, Nicholas G. "Dual-Use and Infectious Disease Research." *Infectious Diseases in the New Millennium*, 2020, pp. 193–215, https://doi.org/10.1007/978-3-030-39819-4_9. Accessed 21 June 2022.

for HIV resistance created mosaic embryos (uneven editing), with unknown potential long-term health impacts on the twins. These risks and concerns are essential to address while ethically governing emerging biotechnologies.

Major parties involved

China

China has been a significant party in conversations regarding the ethical governance of emerging biotechnologies, especially since the Jiankui Scandal of 2018, a Chinese biophysicist announced the birth of the first genome-edited twins. The incident resulted in international criticism, which encouraged the Chinese authorities to become more strict with their ethical review rules at the time and introduce new guidelines for human genome editing, emphasising consent and participant protection. In 2024, China's National Health Commission (NHC) published a new set of guidelines which stressed strict ethical review and updated aspects showing the country's development in the topic and addressing ethical concerns. China maintains these guidelines and has clear conditions for the use of genome editing technologies.

European Union (EU)

The EU's position on the issue of ethical governance of emerging biotechnologies is shaped by EU treaties, the Charter of Fundamental Rights, and the Oviedo Convention, which draws on pre-established principles of the European Convention on Human Rights, in the biology and medical fields. The European Commission also has an independent, multi-disciplinary body called the 'European Group on Ethics in Science and New Technologies (EGE)', which has published its opinions on the ethics of genome editing. The group calls for an inclusive debate on the issue for monitoring collaborations and developing governance rules and regulations with regard to scientific developments. The opinion aligns with typical EU policies, which emphasise precaution, dialogue, and collaboration.

United States of America (U.S.)

The U.S. is a leading country in biotechnology research and commercialisation, and its governance relies on the decisions of federal agencies such as the National Institutes of Health (NIH), which published a paper in 2023 regarding governing biotechnology to provide safety, security, and address ethical, legal and social implications. This paper reaffirmed their current regulations, focusing on product safety rather than process development safety. The nation is heavily interested in maintaining its leading role in the biotechnology industry and acts accordingly with its consistent involvement in the issue. In human genome editing and other emerging biotechnologies, the U.S. has maintained strict limits on heritable genome editing and continues oversight of therapeutic gene-editing.

World Health Organisation (WHO)

The WHO is another highly relevant party in the issue of ethical governance of emerging biotechnologies, as its main task is to encourage the development and testing of new technologies, tools, and guidelines for healthcare management and related issues. This includes the use of biotechnologies in medicine and in food. The organisation acknowledges that emerging technologies have transformative potential in medicine, but only if the associated risks can be identified and fully accounted for. For that reason, in 2024, the WHO published the guideline 'Ethics and governance of artificial intelligence (AI) for health'

aimed to provide governments, tech companies, and health care providers with recommendations on how to protect citizens by using LLMs appropriately. These recommendations include governments developing laws about the use of LLMs in health care and tech companies including qualified medical providers, professionals, and patients in the development of the LLM's application in health care. This guideline was based on a similar guideline published by the WHO in 2021, showing the organisation's recurring involvement in the issue.

United Nations Educational, Scientific and Cultural Organisation (UNESCO)

UNESCO is a key actor in the ethical governance of emerging biotechnologies due to its establishment of the International Bioethics Committee (IBC), a highly relevant committee aimed at exploring the ethical consequences of biotechnology methods like genome editing, and its impact on humans and the environment. The committee, created in 1993, is the only global forum for reflections on bioethics. The Director-General of UNESCO chooses 36 independent experts on life sciences and their applications, who make up the body of the IBC, enabling member states, institutions, specialists or other relevant people to exchange ideas and information in the committee. During their sessions, the committee discusses various bioethical issues to provide ethical recommendations that are adopted by consensus and submitted to the Director-General to share with member states. UNESCO is consistently involved in the ethical governance of emerging biotechnologies and is one of the leading groups in establishing regulations and developing strategic frameworks for ethical applications of biotechnology.

Timeline of events

1975 March 26th The Biological Weapons Convention became effective. Prohibiting development of biological tools for hostile purposes.

1997 November 11th UNESCO adopted the Universal Declaration on the Human Genome and Human Rights.

2003 October 20th The Food and Agricultural Organisation (FAO) adopted the statement on biotechnology. Calling for science-based risk assessment and capacity building in developing countries.

2010 October 15th Nagoya-Kuala Lumpur Supplementary Protocol adopted. Establishing consequences for biodiversity damage caused by living modified organisms (LMOs).

2015 December 1st First International 3-day Summit on Human Gene Editing held in Washington D.C.

2015 November 26th Second International 3-day Summit on Human Gene Editing held in Valencia. Reinforcing the need for international standards on human gene editing.

2019 March 19th The WHO established an expert advisory committee on human genome editing following the He Jiankui case.

2024 July 12th China issues Ethical Guidelines for Human Genome Editing Research, banning heritable clinical applications.

Relevant UN treaties and events

Convention on Biological Diversity (CBD): An international legal framework addressing the conservation of biodiversity. Adopted on June 5, 1992.

Oviedo Convention on Human Rights and Biomedicine: Council of Europe treaty on human rights in biomedicine that restricts genetic interventions in the human germline. Opened for signature on 4 April 1997

UNESCO Declaration on Bioethics and Human Rights: A non-binding declaration that set the precedent for universal principles like human dignity, informed consent, and benefit-sharing to help states in regulating human and life sciences. Adopted on 19 October 2005.

Nagoya Protocol on Access and Benefit-sharing: An international agreement, under the CBD, which aims at sharing the benefits raised from genetic resources fairly and equitably. Adopted on October 29, 2010.

A/RES/73/28; Human Genome Editing: General Assembly resolution establishing an ad hoc panel to assess governance frameworks for human genome editing and implications for global health equity, 4 December 2018.

WHO Framework for Governance of Human Genome Editing: WHO recommendations which outline principles, tools, and governance methods for somatic (body cells) and heritable human genome editing, 3 July 2021.

Dr. He Jiankui Scandal: A Chinese scientist announced, via a MIT Technology Review report, the birth of twin girls whose embryos had been genetically modified for HIV resistance. Making the first known genome editing of humans. This announcement resulted in a lot of criticism due to the doctor's violation of multiple ethical standards, such as parental consent and ethical approval. Announced 25 November 2018.

A/RES/77/261; Promotion of international cooperation in human genome editing: General Assembly resolution inviting states and organisations to cooperate and share information on ethical governance of human genome editing, adopted 30 November 2022.

Previous attempts to solve the issue

China's Post-Dr. He Jiankui Scandal

After He Jiankui violated multiple ethical standards, including manipulating parents into giving consent and not getting approval from the ethics committee, authorities sentenced him to 3 years imprisonment, established mandatory multi level ethical review boards at research institutions, and required all clinical trials involving gene editing to undergo pre-approval by the national ethics committee with public disclosure. However, these measures rely heavily on enforcement capacity and do not prevent similar experiments from being relocated to other jurisdictions, overall not addressing the need for a deeper global agreement about whether any heritable genome editing should be allowed.

WHO Human Genome Registry

A global online platform was launched where researchers self-report all human genome editing clinical activities. WHO verifies submissions and publishes anonymised data quarterly. This registry, though useful for transparency, is voluntary and cannot force all countries to register trials. It does not include any penalties for non compliance, therefore leaves significant gaps in oversight and cannot be considered a binding mechanism.

EU Clinical Trials Regulation with Biotech Annexe

Integrated gene editing trials into the EU Clinical Trials Information System (CTIS), requiring sponsors to submit detailed risk benefit documents, conduct public consultations during Phase I, and undergo joint European level ethical review for cross border trials involving heritable risk technologies. However, this framework only applies within the EU rather than a globally shared standard.

Cartagena Protocol on Biosafety Clearing-house

Created an online portal for risk assessment data-sharing where exporting countries post living modified organism documents. Importing countries conduct Advance Informed Agreement reviews within 90 days, and a compliance committee judges disputes, with 173 countries submitting national biosafety frameworks. However, the system mainly covers the movement of living modified organism documents in the environmental and agricultural context, not much newer applications such as human genome editing.

Possible solutions

Hybrid Global Biotech Oversight Alliance

Establish an international alliance under UN leadership that sets shared minimum standards for safety, consent, and transparency in emerging biotechnologies. States and research institutions that align with these standards receive recognition and incentives (such as funding or smoother cross-border cooperation), while non-compliance results in agreed diplomatic or economic consequences.

AI-Augmented Dual-Use Early Warning Network

Create a global mechanism that uses advanced digital tools to help identify research with potential dual use of high risk applications before it proceeds. Projects flagged as concerning would undergo an additional multi stakeholder review process and temporary pause, while projects that meet agreed safeguards are fast tracked and publicly listed as compliant.

Rotating Global Ethics Tribunal with Veto Power

Set up a diverse expert panel that periodically reviews specific high risk technologies (such as germline editing, gene drives etc) and issues time limited recommendations on whether and how they should be pursued. Its guidance would not automatically override national sovereignty, but states could commit politically to follow these recommendations or to justify publicly when they diverge, encouraging gradual development towards shared norms.

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