

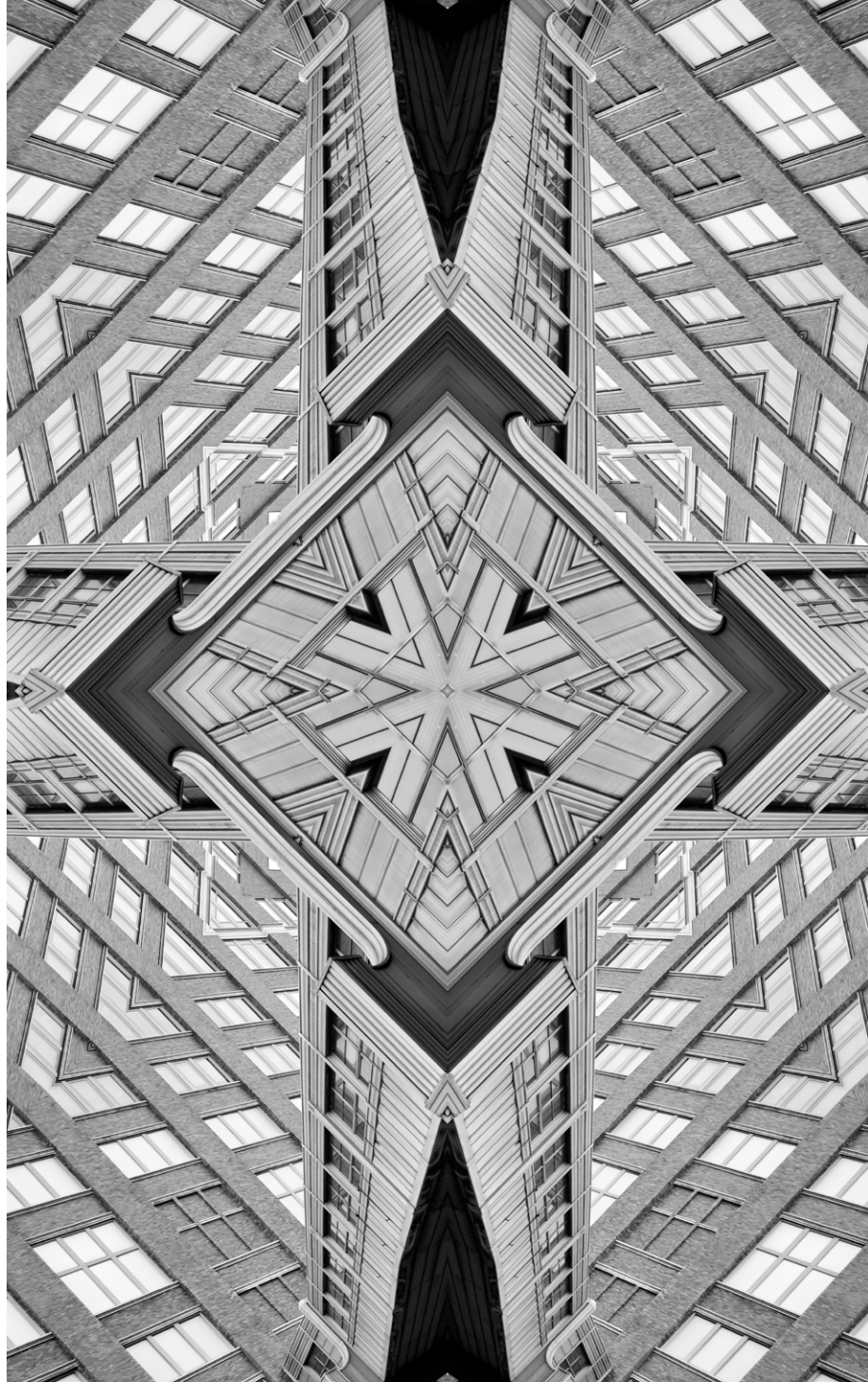
# Issue

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# Brief

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# The Ethical and Security Implications of Genetic Engineering

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## Abstract

The rapid development of genetic engineering technologies has created multiple opportunities for treating genetic diseases and improving human health. However, genetic engineering technology poses ethical, societal, and security challenges. This brief explores these risks, focusing on those related to genetically modified organisms (GMOs) and the revival of ideologies that consider some races to be “more suitable” than others. The brief also discusses security concerns, including the potential for biological warfare and bioterrorism. It underlines the necessity for comprehensive global governance to ensure the responsible and ethical use of genetic engineering technologies to mitigate risks and maximise benefits.

**B** iotechnology is making contributions to science, society, and security by promoting healthcare advancements and food security. The dual-use nature of biotechnology,<sup>1</sup> however, has led to issues such as the development of narcotics and biological weapons.

Similarly of dual use is genetic engineering, most commonly referring to Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) technology<sup>a</sup> that evolved from Zinc Finger Nucleases (ZFN) and Transcription Activator-Like Effector Nucleases (TALENs).<sup>2</sup> In the past few years, CRISPR has led to more precise genetic engineering, including through technologies such as base editing, single nucleotide substitutions, prime editing,<sup>b</sup> and ‘drag-and-drop’ editing for large insertions in Programmable Addition via Site-specific Targeting Elements (PASTE).<sup>3</sup>

As the technology is progressing, critics are calling attention to its potential social and ethical implications, including, for instance, the emergence of the notion of “designer babies”.<sup>c4</sup> The controversy surrounding CRISPR technology expanded in early 2015, both in anticipation of and in response to the first reported use of the technology to genetically modify non-viable human embryos.<sup>5</sup> The debate intensified in November 2018 after Chinese researcher He Jiankui confirmed the birth of twin girls whose genomes had been edited at the early embryo stage to confer resistance to HIV infection. In December 2019, the Nanshan District People’s Court in Shenzhen, China, found He and two others guilty of violating Article 336 of the Criminal Law of the People’s Republic of

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- a Genetic engineering involves manipulating the genetic material of organisms, typically DNA or RNA, and can include adding, deleting, or modifying specific genes to achieve desired traits or outcomes.
- b Editing without double-stranded breaks.
- c This term was introduced with the emergence of CRISPR-cas9 (a sub-type of CRISPR) to refer to genetically altered embryos. The process involves making genetic alterations to in-vitro early-stage embryos or gametes. Genetically modified embryos are then transferred to a uterus to initiate a pregnancy, resulting in the birth of a child with a modified genome. If the child reaches reproductive age and has offspring using their gametes, the descendants will inherit a genetically modified genome. While designer babies were introduced to remove a foetus’s susceptibility to genetic conditions such as certain types of cancers, blood disorders such as HIV, and disorders like Alzheimer’s, Parkinson’s, and Huntington’s, concerns arose on the use of such interventions to alter a child’s physical features, citing eugenics, the removal of segments of the population, and ethics surrounding intervention. See: <https://doi.org/10.1016/bs.pmbts.2021.01.017>; <https://doi.org/10.3906/biy-1912-52>

# Introduction

China, which prohibits engaging in medical activities without a licence.<sup>6</sup> While this is the only reported case so far of CRISPR being used to modify humans, it underscores the potential risks of genetic engineering and the urgent need for governance to ensure the responsible and ethical use of these technologies.

There are many ethical concerns in the field of biotechnology, particularly genetic engineering. For the purposes of this brief, these concerns are categorised into two areas: the social impact of biotechnology and genetic engineering, and their implications for security and warfare. Further, the brief discusses the impact of emerging technologies, existing governing tools, and ways to address gaps.

“Genetic engineering is becoming more precise, and critics are calling attention to the potential social and ethical implications.”

# Social Concerns and Bias

Current conversations around genetic engineering have failed to include its applications and impact on society, security, and modern warfare.<sup>7,8</sup>

The main concerns around genetic engineering include the following:

- **Competitive pressures:** While the primary use of genetic engineering is cited as disease prevention, at a larger scale, there is a risk of participants choosing ‘desirable’ traits to predispose their offspring for success. This can range from sex selection, to physiological traits that are considered attractive, to mental abilities that can influence academic success. Such changes could contribute to the erasure of vulnerable communities and exacerbate socio-economic inequalities through the high cost of treatments.<sup>9</sup> Additionally, ethical considerations often overlook the agency of the individual born from genetic engineering, especially of the cosmetic kind.<sup>10</sup>
- **Resurgence of eugenics:** Heritable human genome editing could promote eugenic ideologies aimed at ‘improving’ humanity, which would further increase stigma against those considered to be genetically disadvantaged, including those with disabilities and oppressed communities, and undermine the fundamental equality of all people. While genetic engineering can be used to target certain diseases and genetic conditions, its use in identifying endogamous communities can impact social equity in the long run. A plausible scenario, for instance, is that health insurance premiums would be calculated based on genetic data;<sup>11</sup> population groups could be intentionally or unintentionally reduced by targeting certain gene pools.<sup>4,12</sup>

“Human genome editing could promote eugenic ideologies aimed at ‘improving’ humanity.”

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<sup>d</sup> While present-day population management is reserved for pests and viruses, the extension of such knowledge to human populations is not impossible.

# Security and the Future of Genetic Engineering

**B**iological warfare (biowarfare), bioterrorism, and biosecurity have been central to security treaties since the 1972 Biological Weapons Convention (BWC).<sup>13</sup> While biological warfare is a low-probability outcome of warfare, the potential use of such agents can have a significant impact.<sup>14</sup> Genetic engineering technologies, particularly those that can modify the human genome, pose unique security risks. For instance, they could be used to create genetically enhanced biological agents that are more virulent or resistant to existing treatments. The concerns around the societal impact and aligned ethical concerns of genetic engineering also extend to biological weapons.

- **Targeting minorities:** Ethnic communities that practise endogamy<sup>e</sup> may have common genetic markers and be vulnerable to the same diseases.<sup>15</sup> These commonalities can make minority groups the target for biological weapons that exploit such disease vulnerabilities. This can include a genetically motivated carrier or delivery system or a genetically enhanced biological agent. In this context, targeting populations based on race, caste, gender, and other sub-groups is not unimaginable.<sup>16</sup>
- **Increasing the virulence of biological weapons through genetic engineering:** Genetic engineering has long been considered a potential tool for creating more lethal biological warfare agents. In 2003, experiments with the mousepox virus showed that inserting specific human genes, such as interleukin-4 (IL-4),<sup>f</sup> intended to boost the immune response, can result in a virus with significantly greater virulence. Comparable results have been observed with Vaccinia virus strains used in smallpox vaccination.<sup>17</sup> Furthermore, genetic engineering could create camouflaged viruses by hiding them within harmless bacteria. Cloning the entire genome of a virus into a bacterial plasmid or using bacterial or yeast artificial chromosomes for larger viruses could be used to create a biological weapon. Additionally, RNA<sup>g</sup> viruses can be generated by cloning the cDNA<sup>h</sup> version of their genome onto a bacterial plasmid, which could pose a significant threat

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e A cultural practice of marrying within one's social group.

f Interleukin-4 (IL-4) is a protein that the human body produces to help fight infections and regulate the immune system.

g Ribonucleic acid

h cDNA stands for complementary DNA. During cDNA synthesis, reverse transcriptase makes a DNA copy of the messenger RNA (mRNA) molecule by using it as a template. The resulting cDNA molecule is a complementary copy of the original mRNA, which can then be used for various applications in molecular biology, such as cloning genes, studying gene expression, and making recombinant DNA molecules.

# Security and the Future of Genetic Engineering

if released into the environment.<sup>18</sup> Advancements in genetic engineering technology have also allowed scientists to replicate the nucleic acids of animals and plants within bacterial cells to enable the study, manipulation, and mass production of highly pathogenic viruses within the protective environment of host bacteria, such as *Escherichia coli* K12 (commonly called *E. coli* K12).<sup>i,19</sup> For instance, genetic engineering enabled the safe study and mapping of the genome of the Lassa fever virus,<sup>j</sup> which is often cited as a potential biological-warfare agent.<sup>20</sup>

“Genetic engineering technologies could be used to create genetically enhanced biological agents that are more virulent.”

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- i While *E. coli* is a bacterium commonly found in human and animal intestines, *E. coli* K12 is a specific strain of *E. coli* that has been modified to make it useful for scientific experiments. Scientists can genetically modify *E. coli* K12 to produce specific proteins, enzymes, or other molecules for research purposes.
- j An RNA virus with no current treatment available, often transferred to humans through rodents or infected foods.

# Machine Learning and Genetic Engineering

The fusion of Artificial Intelligence (AI) and biotechnology presents multiple opportunities, from regenerative medicine to drug discovery and healthcare. Indeed, the use of AI in biotech has resulted in innovations like the Xenobots, created by the University of Vermont in 2020.<sup>21</sup>

AI has the potential to revolutionise healthcare by enabling personalised medicine. By analysing genetic data and biological markers, AI can predict disease susceptibility, recommend interventions, and optimise drug development and consumption.<sup>22</sup> Moreover, AI can analyse health records to predict disease outcomes and susceptibilities in larger populations, enhancing healthcare delivery and public health initiatives.

Machine Learning (ML) and AI can positively impact co-advancement, environmental impact, climate impact, and agricultural protection. However, this convergence also raises ethical and regulatory concerns, including the potential for discriminatory practices. In India, for example, issues with pharmacogenetic diversity<sup>k</sup> would disadvantage southern populations, tribal groups, and certain disadvantaged castes that have fewer commonalities with European populations than northern Indian populations.<sup>23,24</sup> AI can also be misused for the development of targetable biological agents.<sup>25</sup>

“The fusion of AI and biotech presents opportunities and risks.”

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<sup>k</sup> Pharmacogenetic research refers to the genetic disposition of individuals to respond to medicines and drugs in certain ways. Diversity here is important to ensure drug development does not feature a bias to a community.



# Existing Standards and Mechanisms

**G**lobally, genetic engineering has variable dimensions, which are highlighted in domestic governance tools. For example, in Germany, human genome editing is a function of medicine, does not consider negative intentional and unintentional outcomes that can improve individual health, and is assessed based on a constitutional commitment to human dignity.<sup>26</sup> Meanwhile, Canadian law around genetic engineering focuses on assisted reproduction while safeguarding diversity and human integrity.<sup>27</sup> In the United States (US), the Food and Drug Association (FDA) has the primary authority to regulate clinical genome-editing applications, focusing on the safety and efficacy of cloning for food and therapeutic applications.<sup>28</sup> For their part, the 29 European Union (EU) countries that ratified the Oviedo Convention<sup>1</sup> consider human rights, human dignity, and genome integrity as fundamental.<sup>29</sup>

Countries have varying policies on germline genome editing. Many countries prohibit using genetically modified embryos for heritable genome editing, although no country explicitly allows heritable human genome editing.<sup>30</sup> However, this is hard to monitor. The heritability of genetic engineering can only be studied across generations, and the novelty of the technology makes off-target heritable impact plausible.<sup>31</sup>

Recent developments necessitate an understanding of the global policy landscape for heritable human genome editing, the possible repetition of such experiments, and growing public interest and policy considerations. In this context, there are multiple international standards and dialogues that oversee this subsection of modern biotechnology.

## Asilomar Conference

The emergence of Recombinant DNA (rDNA) technology in the early 1970s allowed the manipulation of DNA through inserting genes from one organism into the DNA of another. In this context, the Asilomar Conference on Recombinant DNA, held in February 1975 in California,<sup>32</sup> aimed to assess the risks of rDNA technology and establish guidelines for safe and restricted use.<sup>33</sup> The main concern was the GMOs escaping from laboratories in unintentional leakages, potentially causing ecological disasters or the creation of harmful pathogens.

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<sup>1</sup> Officially known as the Convention on Human Rights and Biomedicine, it is an international treaty established by the Council of Europe in 1997 on protecting human rights and dignity in the context of biological trade, biotechnology and developments of medicines and treatments. The convention is discussed further in the brief.

# Existing Standards and Mechanisms

The Asilomar Conference highlighted the importance of scientists taking responsibility for the ethical and safety implications of their research. The conference was attended by over 140 scientists and stakeholders, who formulated guidelines that are considered even today.<sup>34</sup> The conference established research guidelines describing containment styles for defined risks, including minimal, low, moderate, and high risk.<sup>m,35</sup> It also laid the foundation for a biotechnology and genetic engineering regulatory framework and led to the establishment of the Recombinant DNA Advisory Committee (RAC) at the National Institute of Health (NIH), which oversees recombinant DNA research in the US.<sup>36</sup>

## Oviedo Convention

The Oviedo Convention, formally known as the Council of Europe Convention on Human Rights and Biomedicine, is an international treaty to protect human rights and dignity in biomedicine.<sup>37</sup> It was adopted in 1997 and enacted in 1999 for members across Europe.<sup>38</sup> The Convention aims to safeguard the dignity and fundamental rights of individuals involved in biomedicine and establish common ethical principles and standards for medicine and biomedical research<sup>39</sup>—the first such in biomedicine. It includes critical provisions for required informed consent for medical interventions and research involving human subjects, protections for vulnerable individuals, and the privacy and confidentiality of medical information.<sup>40</sup> Further, it prohibits human cloning for reproductive purposes and the modification of the human genome in germ cells, along with additional protocols for biomedical research and genetic testing.<sup>41</sup> The standards are mandatory for member states, which are encouraged to ratify the Convention.

## ISSCR Guidelines

The International Society for Stem Cell Research (ISSCR)<sup>n</sup> Guidelines aim to ensure responsible research and clinical translation of stem cell-based therapies.<sup>42</sup> The guidelines cover areas such as ethical standards, research oversight, informed consent, responsible communication, and clinical translation.<sup>43</sup> The

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m Minimal risk: Might be biohazards but can be contained once detected; Low risk: Experiments that may result in novel biotypes that do not have an ecological impact or increased pathogenicity; Moderate risk: The possibility of a biotype that is novel and highly pathogenic; High risk: The possibility of a biotype being highly pathogenic and having an immense ecological impact.

n The ISSCR is an international organisation that promotes stem cell research and its applications in treating diseases. While the organisation is not a governing body, it has influenced both domestic policy and private sector participation.

# Existing Standards and Mechanisms

ISSCR Guidelines are regularly reviewed and updated to reflect scientific developments and ethical considerations and serve as a global standard for ethical conduct in stem cell research.<sup>44</sup> They also conduct lobbying efforts to develop regulations governing stem cell research and therapy, including policy lobbying and advocacy in the US and the European Union (EU).<sup>45</sup> ISSCR's recent lobbying in Australia resulted in the establishment of a framework for stricter regulations concerning the marketing and administration of unproven therapies of autologous human cell and tissue products.<sup>46</sup>

## **BERGIT**

The Berkeley Ethics and Regulation Group for Innovative Technologies (BERGIT) is a project co-hosted by the Kavli Center for Ethics, Science, and the Public and the International Genomics Institute.<sup>47</sup> BERGIT holds regular meetings with member scientists to discuss ethical concerns in contemporary times. Although BERGIT has not published a list of standards, it has had a notable influence in participation and discussion on emerging technologies and the applications of biotechnology; an example are the recent discussions on AI and digital information, genome editing therapies, and neurotechnology.<sup>48</sup>

## **UNESCO's International Bioethics Committee**

In 2003, the United Nations Educational, Societal and Cultural Organization (UNESCO) established the International Bioethics Committee to explore the ethical implications of genome editing and its impact on human rights, human dignity, and the environment.<sup>49</sup>

## **World Health Organization**

The World Health Organization (WHO) has convened expert panels and working groups to develop guidelines for the governance and oversight of human genome editing. Their recommendations emphasise transparency, inclusivity, and international cooperation to ensure the responsible and ethical use of genetic engineering technologies. WHO has a list of considerations for countries that are in the process of establishing guidelines in biologics.<sup>50</sup> While this document calls for ethical considerations in regulatory applications at domestic levels,

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<sup>o</sup> The Innovative Genomics Institute is a joint effort between scientific research institutions on the West Coast of the US and was founded by Jennifer Doudna, Nobel Prize winner and a pioneer in genetics and biotechnology work.

# Existing Standards and Mechanisms

these ethics are not clarified. Additionally, WHO and UNESCO established the international, non-profit Council for International Organizations of Medical Sciences (CIOMS) in 1949 to govern health research and genetic engineering.<sup>51</sup> The CIOMS developed a comprehensive document on ethical guidelines for human impact studies, “International Ethical Guidelines for Health-related Research Involving Humans”, that encourage countries and private-sector participants to implement controls on clinical research, highlight the need for informed consent and benefit sharing, and encourage reimbursement for participation in different types of human-based research trials.<sup>52</sup>

## **International Commission on the Clinical Use of Human Germline Genome Editing**

The International Commission on the Clinical Use of Human Germline Genome Editing was formed by the US National Academy of Sciences, the US National Academy of Medicine, and the UK’s Royal Society.<sup>53</sup> The Commission developed a report that outlines the principles, criteria, and a framework for the clinical use of germline genome editing, emphasising the importance of safety, efficacy, and responsible conduct. However, its recommendations for neutral ethics without regular renewal have been criticised for including diseases that have alternative cures and for overlooking social aspects such as affordability and accessibility.<sup>54</sup> At the same time, the whistleblower feature in the report reduces the possible misuse of such technologies, thus increasing its relevance.

## **Security Standards**

Although emerging technologies and alliances are an intuitive next step in the future of warfare, security guidelines are yet to account for genetic engineering, being restricted by proxy due to existing standards on scientific limits on research and trade limits on biological agents. The potential societal harm from genetic engineering and its implications for the future of warfare and security necessitate an urgent examination of these issues.<sup>55</sup> Although there are no specific international ethical guidelines around the use of genetic engineering in warfare, such use of modern biotechnology violates existing international conventions.

- The Biological Weapons Convention (BWC) is an international treaty with 187 parties and four signatories that prohibits the development, production, and stocking of biological agents that could be used as biological weapons.<sup>56,57</sup> Genetically engineering a biological agent of increased virulence would violate this convention.

# Existing Standards and Mechanisms

- The Chemical Weapons Convention (CWC) is an international treaty that prohibits the development, production, stockpiling, and use of chemical weapons and has 193 state parties.<sup>58</sup> While the CWC may not directly relate to genetic engineering in warfare, enhancing the lethality or effectiveness of chemical weapons by targeting vulnerable genomes or genetic groups would likely be considered a violation of the convention.
- The International Humanitarian Law (IHL) is a public international law that regulates the conduct of armed conflict and seeks to protect civilians and combatants who are *hors de combat* (out of the fight). The use of genetic weapons, such as genetically modified pathogens, would violate the principles of IHL, including the prohibition against indiscriminate attacks and the ban on biological weapons that cause suffering.<sup>59</sup>

Further, research that may result in the creation of genetically motivated weapons would also fall under existing guidelines. Scientific organisations, such as the International Committee of the Red Cross (ICRC),<sup>60</sup> the World Medical Association (WMA),<sup>61</sup> and the International Science Council (ISC),<sup>62</sup> have ethical guidelines that prohibit the use of science for harmful purposes. The code is not legally binding but acts as a standard for medical professionals and other stakeholders.

The National Academies of Sciences, Engineering, and Medicine, by request of the US Department of Defense, formalised the Imperiale Framework in 2018.<sup>63</sup> The framework's primary objective is to monitor advancements in biotechnology and its implications in warfare.<sup>64</sup> The framework has identified three areas of concern: recreating known pathogenic viruses, making existing bacteria more dangerous, and creating harmful biochemicals via in-situ synthesis. The first two rely on technology that is easy to use and highly accessible, while the novelty of the third makes preventing and recognising an attack difficult.<sup>65,66</sup>

“Security guidelines are yet to account for genetic engineering.”

# Regulatory Gaps and Ethical Guidelines

**E**xisting regulatory tools that place limits on the development and use of dual-use biotechnology tools are outdated and do not discuss the potential of genetically enhanced bioweapons or chemical weapons. The gaps in standards are described in the following points:

- **Exclusivity:** While many standards include dialogues between scientists, the inclusion of policymakers and democracy experts across countries has been lacking. For example, the Asilomar Conference has been criticised for its exclusivity, ignorance of citizen representation, and neutral approach to ethics.<sup>67</sup>
- **Limited scope:** While more recent dialogues highlight the importance of ethical considerations in genetic engineering, global treaties, including the Asilomar Conference, continue to have a narrow focus on scientific safety concerns without adequately addressing the broader ethical, social, and environmental implications of rDNA technology.<sup>68</sup>
- **Insufficient regulation and speed of progress:** Existing guidelines are broad and do not discuss the applications of technologies. Further, the voluntary moratorium on participation has slowed the governance of scientific progress in biotechnology.<sup>69</sup> This is especially true in the EU, where member states are undersigned to the Oviedo Convention.
- **Reductive definitions:** Existing regulatory tools prohibit the development of harmful biological agents or gene modification through genetic engineering, often citing human dignity and identity. However, this approach also poses the risk of biological definitional reductionism. For example, the concept of human dignity, as outlined in the Oviedo Convention, suggests a direct link between human dignity and the biological structure of human beings.<sup>70</sup> However, these definitions do not discuss the indirect impact on human safety caused by viruses that target agriculture or animals, which then impact food supplies and ecosystems.<sup>71</sup>
- **Over-reliance on member state regulations:** Existing frameworks of biotechnology law rely on member states' adoption of treaty guidelines and the creation of domestic regulation, monitoring methods, and implementing standards.

# Regulatory Gaps and Ethical Guidelines

- **Over-reliance on co-existing treaties:** Most treaties and international regulatory tools rely on each other to form a comprehensive framework. However, none of them discuss emerging technologies or genetic engineering directly. Moreover, the applications of traditional biotechnology and newer forms of gene modification and their implications on security are not addressed. Although the governance of such technologies as a function of science and innovation will ensure compliance by researchers and scientists, it will exclude the control of potential dual-use outcomes. Genetic engineering must therefore be explicitly considered in regulatory tools and treaties. Additionally, the BWC, along with other regulations like the CWC and Convention on Biological Diversity, must be expanded to discuss gene modification in warfare and security.

“Genetic engineering must be explicitly considered in regulatory tools and treaties.”

# Recommendations for Governance

The use of modern technologies in warfare is inevitable. Banning technology use is often ineffective, not only because bans discourage innovation but also that they target only those who already function under regulations. States that do not comply, or non-state actors who have access to emerging technologies, will remain ungoverned. However, introducing ethical guidelines and standards can control the research that drives such use. Most standards already cover beneficence and non-maleficence—that is, genetic engineering should promote the well-being of individuals and society.

The US has established a National Security Commission on Emerging Biotechnology (NSCB), which focuses on biosecurity, including genetic engineering.<sup>72</sup> Other domestic governments, however, continue to rely on existing global governance tools. While other countries need to set up national security commissions similar to the NSCB, this needs to be supplemented by enhancing existing governance tools to achieve holistic and well-thought-out innovations in biosecurity.

Existing treaties oversee genetic engineering as a science and attempt to maintain ethics in research, and the BWC oversees the existence, development, and use of biological agents. However, these need to expand to include genetic engineering, its co-existence with emerging technologies like AI, and its relationship with biological and chemical weapons. A regulatory tool for genetic engineering should thus include the following:

- **Transparency and informed consent:** All parties involved, including researchers, participants or donors, and affected communities, should have access to clear and accurate information about the genetic editing process, its potential consequences, and its intended goals. Informed consent must be obtained from individuals subjected to genetic engineering, ensuring that they fully understand the implications.
- **Inclusivity and public engagement:** Decisions about genetic engineering should involve multiple stakeholders, including scientists, ethicists, policymakers, affected communities, and the public. Public engagement and open dialogue can help ensure that decisions are made collectively and with diverse perspectives.
- **Equity and justice:** Genetic engineering should not exacerbate social disparities or inequalities. Access to genetic engineering technologies and therapies should be available to all, regardless of socio-economic status, ethnicity, or other factors. Efforts should be made to ensure the fair distribution of benefits and risks. Additionally, an ethics committee



# Recommendations for Governance

should be established to ensure that genetic engineering does not erase communities and traits that may not be considered “desirable”. This would require regular discussions on which genes are perceived as “good” or “bad”.<sup>73,74</sup>

- **Proportionality and precaution:** Researchers and practitioners should exercise caution and weigh the potential dangers of genetic engineering against the possible benefits towards minimising potential harm. Such proportionality can also be used to address the risk levels of biological agents and technologies in use and grade them to standardise the risks that should be avoided without verified benefits over costs.
- **Product-driven over process-driven governance:** Domestic, regional, and international regulations and treaties should govern genetically engineered products alongside the ethics involved in the process. Being of dual use, the products and their application require greater oversight than the process alone.
- **Environmental responsibility:** Genetic engineering guidelines should consider potential short- and long-term environmental impacts. Genetic modifications that could affect ecosystems or species should be thoroughly evaluated and, if necessary, regulated to prevent unintended ecological consequences. Here, bioterrorism cannot exclude agroterrorism and its indirect impact on humans through targeting genetic markers in ecosystems and food chains.
- **Long-term monitoring and research:** Genetic modifications can have long-lasting effects that may not be immediately apparent. Continuous monitoring of individuals via a research organisation that reports to a global agency similar to BERGIT or ISSCR can aid in the assessment of the long-term impact of gene-edited organisms or therapies and address any unforeseen issues.
- **Global collaboration:** Efforts should be made to harmonise ethical guidelines and domestic regulations internationally to prevent regulatory arbitrage and ensure consistent standards.
- **Moratorium on certain applications:** In some cases, it may be necessary to implement temporary moratoriums on specific genetic engineering applications until the technology is better understood, potential risks are mitigated, and ethical considerations are addressed.

# Conclusion

**T**he rapid advancement of genetic engineering technology and its derivatives has raised ethical, societal, and security concerns. While these technologies hold promise for treating genetic diseases and improving human health, they also present risks, such as the largely yet-unknown effects of GMOs and enhancing bioweapons.

Existing regulatory frameworks, such as the Asilomar Conference guidelines, the Oviedo Convention, and the ISSCR Guidelines, provide a foundation for governing genetic engineering technologies. There are gaps in these regulations, however: their definitions are reductive, they lack comprehensive ethical principles, and they overlook security-based applications. The BWC should be expanded to address these challenges and establish comprehensive governance frameworks for genetic engineering to prioritise transparency, informed consent, equity, and environmental responsibility.

These frameworks should include long-term monitoring, public engagement, global collaboration, and temporary moratoriums on specific applications. Additionally, governance should be horizontally integrated, focusing on process and application areas to ensure consistent standards and prevent regulatory arbitrage. [ORF](#)

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