

# <u>The Ethics of Human Genetic</u> <u>engineering for medical purposes.</u>



**Tables of contents** 

Overview	2
Definitions of important terms	4
Timeline of key events	5
Position of key nations	7
Suggested solutions	11
Bibliography	13



## **Overview**

Human genetic engineering for medicine is the area of study that explores the latest achievements in the science of genetic alterations, combined with the complex moral implications. The inevitable advance of technology creates the possibility of genome editing with no boundaries more and more serious questions about what shall stay and what shall change are being raised. How far should we go in interfering in the biological processes of creation and with what consequences it will have for all of us? What actions & principles should guide this effort? The following lens follows through with the whole ethical medical of human genetic engineering picture showing the main issues, the historical aspects, and envisioning the scientific interests that exist in the field today. [1]

As the name implies, the main subject matter of human genetic engineering aims at genetically altering an individual's genes via genome editors like CRISPR-Cas9. [2] The goals could be to correct or eliminate genetic diseases and defects that are responsible for numerous diseases and give healthcare for some inherited conditions a new chance. Additionally, when it comes to medical interventions, these questions reach beyond the scope of a single medical intervention as they connect to the wide areas of human identity, autonomy, and societal values.

The ethical discussion of human genetic engineering goes back to a personal obligation to benefit, not to cause harm, refrain from paternalism, make things equal, and respect each person. The possibility of making genetic diseases disappear and also to enhance our capabilities may seem a good thing and the risks involved, such as off-target genetic changes that weren't planned for and unknown health side effects, should be considered. It is important to achieve the delicate balance of the likely advantages and the internal factors that play an important role in medical research and guidance. [3]



It behooves us to discuss the ethical applications of human genetic engineering not only in the context of our current time but also in light of the historical events that are the bedrock of today's canvas. Scientific breakthroughs mark the way progress has been accompanied by ethical deliberations and regulatory checking ranging from the description of the structure of the DNA to the production of the recombinant DNA technology and the advent of CRISPR-Cas9. The comprehension of such a timeline plays a role in developing a clear picture of the moments of ethics at which the field stands currently.

Furthermore, the review will consider how the view of some nations is on human genetic engineering, with the factors of their culture, religion, and society as the cause for the varied responses. Genetic variations in the regulatory framework and the public attitudes to genetic engineering, as well as the country differences in governmental policies, reveal the fact that the main obstacle to the progress of science is the achievement of comprehensive consensus towards body alteration. [4]

In the course of doing this complex landscape, the report will come with some effective resolution multifaceted most of which are the ethical challenges associated with human genetic engineering for medical purposes. These measures intend to promote more conscientious research ethics, guarantee that genetic technologies are made available to everyone, and preserve the norms of confidentiality and informed consent.

Traveling through the ethical universe of human genetic engineering is an act that calls for prudent contemplation, sharp moral character, and a dedicated stance to assure prudence and compassion in the trial of markets already known.



## **Definitions of important terms**

#### **Genetic Engineering:**

Human being engineering commonly known as recombinant DNA technology is the deliberate manipulation of an organism's genes with biotechnological methods to achieve a specific outcome. This distinction for the medical use of human gene modification depends on the precise detail of alterations of the human genome which are limited to the correction or modification of genetic traits related to specific illnesses or conditions. Looking at the recent arrival of technologies such as CRISPR-Cas9, a lot has been achieved concerning the area of genetic engineering, which now provides for very precise and effective modifications to the sequence of DNA. [5]

#### **CRISPR-Cas9:**

CRISPR/Cas9, or Clustered Regularly Interspaced Short Palindromic Repeats and CRISPR-associated protein 9 is a new and different tool that allows to directly modify genes. While using CRISPR, researchers can edit their genes with a high degree of accuracy as it focuses on specially designated sites on DNA molecules. The Cas9 enzyme works as a molecular scissor, making its incision at the expected genomic location. This technology encloses a great amount of eminence and effectiveness being used in the field of genetic modification, which has brought along new approaches toward the treatment of diseases.

#### **Recombinant DNA Technology:**

Recombinant DNA technology makes it possible to join DNA fragments that normally would not occur together in the genome by using two strands of DNA. This technology is the basis of the methods of genetic modification currently deployed in the industry and of those previously used in the development of medical treatments and therapies. Recombinant DNA technology interacts closely with human genetic engineering as it enables the modification and manipulation of chromosomes, which is considered a human genome. [6]



#### **Informed Consent:**

When we talk about medical ethics, informed consent is an essential component of the ethics of medical procedures and research which underscores the dignity, and autonomy of individuals. Gaining informed consent as we apply human genetic engineering is to include the individuals to be given complete details concerning the nature, purpose, risks, and potential benefits of genetic intervention at the same time. It is vital to educate people about the consequences of genetic modifications, as it is the right of the people to make informed decisions and keep their autonomy. [7]

#### **Off-Target Effects:**

Undesirable from a therapeutic angle, the off-target effect scenarios encompass less specific modifications made to the genetic material in locations other than the premeditated target site. In regard to CRISPR-Cas9 and other gene editing tools, specific instances where the technology edits genes that were not a target of it are off-target effects. These are ethical considerations. Such unforeseen alterations may experimentally have surprising results, hence raising the difficulty of the safety concern over the possible long-term adverse effect of genetic manipulation. [8]

#### **Genetic Therapy:**

Genetic therapy holds a promise that is not vested in the use of genetic engineering tools that are employed to alter the genetic material of an individual to either treat or prevent diseases. The latter involves the treatment of any genetic abnormalities at the primary level. As a result, it lessens the risk of any side effects that could arise and offers more targeted and effective treatment. Ethical issues related to genetic engineering epidemically involve the accessibility of therapies, the equitable distribution of resources, and the long-term safety of the treatment. [9]



# **Timeline of key events**

## **1972 : Asilomar Conference**

The Asilomar Conference occurring in 1972 and involving scientists together to discuss ethical issues related to recombinant DNA technology is one of the important milestones in the development of the field. It delivered the foundation for people to acknowledge the might of responsible genetic engineering. [10]

# **1981:** The application of recombinant DNA in mice in genetics leads to a facile understanding of this subject.

In 1981, scientists exposed mouse embryos to a rabbit along  $\beta$ -globin gene copy, and the genetically inherent lineage of mice was successfully altered, proving that mammals, including humans, can be genetically edited.

# **1982: First Genetically Engineered Human Drug - Synthetic Insulin**

At Genentech, Dennis Kleid, one of the scientists, played a critical role in testing the first time that the genetically engineered human drugs underwent a clinical trial against diabetes by developing synthetic insulin. On the other hand, this can be considered as a turning point in biotechnology development when the insulin formerly harvested from animals, was now produced via gene engineering. By creating a synthetic version of it, the shortfall to health conditions like Type I diabetes which requires insulin was removed, and the use of animal sources was eliminated.



### 1986: First Recombinant Vaccine for Humans is Approved

Achievements in vaccine development have been made by scientists around the globe by creating the very first recombinant vaccine for Hepatitis B. Pablo D. T. Valenzuela succeeded in producing the vaccine, using yeast cells, and was the first to do so thus setting a new standard in vaccine technology. The innovative discovery proved the basis for the invention of many gene recombinant vaccines, for instance, HPV, pertussis, and meningococcal.

### **1993: Discovery of the Principles of CRISPR**

During the same period when CRISPR is known now due to the Jennifer Doudna and Emmanuelle Charpentier studies, the researchers in the Global South, including Francisco Mojica, made an earlier discovery of CRISPR. Mojica noted DNA segments containing several repeated DNA sequences in bacteria after examining them. A little later, he realized that the repeat structure protected those cells from the viral attack. This groundbreaking discovery formed the base for the following decade of progress in the field of DNA research.

#### 1994: Flavr Savr Tomato

From genetically modified crops we can take the Flavr Savr tomato, the first genetically modified crop, as an example which won the market in 1994. This was a revolution in farming and drew the attention of many environmentalists and food scientists to the impact and safety of food.



## 1996: The Cloning of Dolly the Sheep

In 1996, cloning made history when scientists from the Roslin Institute and Ian Wilmut led the process that resulted in the creation of Dolly the Sheep. Dolly was not only the first animal ever to be cloned but also an adult cell that made it possible to clone species which doesn't naturally occur(plus) The first cloning of an endangered species proved to be a breather for the conservation industry exploring genetic sustenance.

# **1999: History of Genetic Engineering in Humans is Made when the First Human Chromosome is Sequenced**

In 1999, some of the scientists doing the work behind the Human Genome Project succeeded in a major step by demonstrating complete sequencing for chromosome 22. This breakthrough stands as a significant milestone in the area that has been worked on since 1988 and is funded by the United States Congress. The study manages to bring to light the method of sequencing DNA and the link between human genes and diseases.

### 2000: Human Genome Project

Fulfillment of Human Genome Project in 2000 provided the complete description of the sequence of the DNA and its subsequent mapping was an important step towards the personal medicine that led to the ethics controversies.



## 2006: FDA Approval of the First Preventative Cancer Vaccine

In 2006 the FDA got a breakthrough in cancer prevention with the approval of Gardasil. This vaccine, which was developed with gene-editing tools and protected against human papillomavirus (HPV), is now the first cancer vaccine used for prevention. With the significant performance, the vaccine (Gardasil) was initially approved for females within the age range of 9 to 26. In later years, the approval was expanded to include both males and females who are up to 45 years of age.

### 2010: The World's First Synthetic Life Form

As the 2010,s decade in the world began, scientists from around the world made the first of their synthetic forms of life. A group of scientists headed by Craig Venter sorted building blocks and manually built a synthetic chromosome which then was transplanted into a bacterial cell forming a whole new life. It has been proved that synthetic biology enables gene manipulation, which can be used in genetic engineering.

### 2012: Discovery of CRISPR Genome Engineering Tool

Of CRISPR technology Jennifer Doudna, Emmanuelle Charpentier, and their team, in 2012, described its fundamental chemical process. This bacterial adaptive immunity was juxtaposed with gene editing, which made it possible to have absolute precision in making the modifications in eukaryotic DNA. CRISPR-Cas9 has taken the gene engineering world by storm with its outstanding precision and flexibility by going to the medical field and agricultural sector, among others.



## 2015: First GMO Salmon Sold in Canadian Markets

The commoditization of transgenic animals came alive in 2015 when genetically modified salmon became the first organism of this kind to be sent for commercial sale, in Canada. Developed by AquaBounty stands as proof of the research lasting over 25 years, and introduced a solution that may help reduce overfishing.

## 2017: The first CAR T Therapy for Cancer is Approved

CAR T Cell treatment milestone was reached in 2017 with the FDA's approval of two therapies. These remedies, licensed for use in children with acute lymphoblastic leukemia and advanced lymphoma in adults, proved very rapid and highly successful regarding tumor ablation. Gene targeting as a mechanism of CAR T therapy advanced a modality of molecularly precise anticancer treatment.

### 2018: First Human Trials for CRISPR are Approved

In 2018 for the very first time in the clinic's history, the therapy of CRISPR-based treatments was approved and served as a milestone toward the translation of these gene-editing technologies into clinical application. Through clinical trials, Vertex Pharmaceuticals and CRISPR Therapeutics started unleashing an experimental therapy meant to cure beta-thalassemia, and this gave hope to everyone who will have to treat genetic disorders in the future.

### 2018: CRISPR-Edited Babies

He Jiankui, a Chinese scientist openly claimed having created gene-edited babies in breach of scientific ethics and principles utilizing CRISPR-Cas9 method, provoking international rebuke in 2018.



## 2019: He Jiankui's Sentencing

In 2019, the government of China sentenced He Jiankui to 3 years behind bars for his contribution to the practices of gene editing, and hence they pointed out the importance of legal consequences.

## 2020: COVID-19 mRNA Vaccines

Something notable that COVID-19 mRNA vaccines demonstrated in 2020 is how they served and pushed the bond between genetic technologies and public health, and the possibilities for responsible application.

# **2020:** The Year of CRISPR: Nobel Prize, Success of Clinical Trials and More

2020, with its pioneering role in the use of CRISPR technology, turned out to be a landmark year. Clinical trials with subjects under the treatment of CRISPR-based therapeutics had a positive result, with patients taking a big step forward after the administration of the drug. Following treatment of the first patient to suffer from the disease, namely Victoria Gray, increases in fetal hemoglobin levels were observed, in addition to the relief of pain. The Nobel Prize in Chemistry was also awarded to Emmanuelle Charpentier and Jennifer Doudna whose research on CRISPR had revolutionized the field.

## **2021: AI-Generated Genetic Sequences**

Utilizations of AI enabled scientists to create gene sequences by 2021. This caused anxiety regarding the fact of whether the advancement made in genetic engineering can be misused and if it is ethically correct to make such synthetic improvements on human beings. [11]



# **Position of key nations**

## **United States:**

Being a leading medical research and technology country, the United States plays a special part in the creation of the ethics of human genetic evolution. At the country level, cutting-edge healthcare services and a well-developed biotechnology industry do exist. The second issue it tackles is the ethical issues around who is going to receive these and how they can be distributed equally. Unresolved questions on providing egalitarian medical care, based on economic status, will constitute the core of US politics.

#### China:

One of the key countries in this field is China which has witnessed dynamic growth of both economy and investment in research and development. Therefore, with the recent investment of China into this field, we can say that it is now a key player in human genetic engineering. The country tries to reconcile this paradox of accelerating technological advances and ethical regulations. Ethical discussions in China mainly concern the questions that deal with informed consent, private matters, and possible misuse of knowledge in the field of genetic technologies. Ethics becomes the center of the nation's attention, and its inhabitants seek the consonance of the global ethical framework.

## **European Union (EU) Nations:**

The development of human genetic engineering has already posed many ethical dilemmas to the EU states, which are represented by EU nations like Belgium, France, and others. And that, countries with stable healthcare systems often become the interlocutors in the process, and so review both useful and harmful use of such medical technologies. EU, regarding this issue, stands for the development of the ethical standards of thus: protection of private life, no discrimination, and openness in genetic research.



#### India:

Like others, India faces ethical questions related to human genetic engineering. It faces a unique situation due to its rapid socio-economic development. The state's statement stresses the point of involving the area of responsibility in research and development taking into account the social and economic diversity of its citizens. India aims at a perfect balance between the flow of technologies and the ethical viewpoint that humans are superior to any other living things by seeking advantages for all in society.

#### Singapore:

Singapore is one the most important contributors to the worldwide widespread of genetic research. The country, having a first-class healthcare regime, tends to center its attention on ethical rules founded on genetic engineering. Singapore supports worldwide systems integration to shape virtuous ethical codes that will responsibly guide the use of biotech.

#### Japan:

Being one of the leaders in the healthcare system, Japan actively contributes to the ethical talk surrounding human genetic engineering. The country gives top priority values to the implication of social-cultural dimensions of such genetic therapies. Japan asserts the need for ethical standards compatible with diversity or else the genetics technology would be inconsistent with the cultural values as well as ethical principles.

### **Russia:**

Russia holds a distinctive perspective on human genetic engineering, emphasizing national sovereignty in ethical decision-making. While recognizing potential benefits, Russia advocates for robust regulations to prevent misuse. The nation actively engages in global discussions, emphasizing the balance between scientific advancements and ethical considerations. This stance reflects a commitment to ethical use while respecting individual nations' sovereignty in shaping their ethical frameworks.



## **Developing Nations:**

Nations facing economic and healthcare challenges, such as Haiti, Ethiopia, Afghanistan, Nigeria, Eritrea, and others, emphasize the importance of addressing disparities in the ethical implications of genetic engineering. These countries advocate for international collaboration to bridge the gap between medical advancements in developed and developing regions. Issues of affordability, accessibility, and ethical guidelines take center stage in their perspectives.



# **Suggested solutions**

The ethical issues in genetically engineering humans for medicinal purposes, preview a complex multidimensional approach. The following suggested solutions aim to navigate the complexities of this field while upholding ethical principles:

#### **International Ethical Guidelines:**

The collaboration of nations should be geared towards documenting ethical guidelines that are comprehensive when it comes to human interventions. Such an effort should include the participation of scientists, ethical committees, decision-makers, and representatives from various cultures to come up with international standards.

#### **National Regulatory Frameworks:**

National entities have to put in place strict regulatory guidelines identifying issues that arise in human genetic engineering. They should state perimeters of ethical standards and practices, as well as stipulate penalties for prohibited acts, but at the same time maintain this balance between scientific progress and ethics.

#### **Public Engagement and Education:**

Collaboration by many stakeholders including governments, scientific communities, and public institutions is needed to raise public awareness. Through a wide availability of relevant data, setting out ethical principles, and creating platforms for the community to engage in the development of genetic engineering are milestones of this initiative.

#### **Ethics Review Boards:**

The formation of independent boards of ethical review is crucial as it does the due diligence of testing the integrity of scientific research and its applications in human genetic engineering. Therefore, it needs these boards to consist of multidimensional specialists to assess the ethical implications, possible risks, and societal impacts of the proposed missions.



#### **International Collaboration and Information Sharing:**

Enabling international harmonization and providing information sharing are crucial in this regard to form a unified ethical canon of AI. Collaborations amongst scientific communities, governments, and institutions on the sharing of insights, results, and ethical best practices may help establish ethical standards.

#### **Inclusive Decision-Making Processes:**

The decisions involving human genetic engineering should emphasize the inclusiveness of the decision-making processes. The approach that ensures diversity – culture, geography, gender, and moral values to understand the issues extensively and to engage effectively in the debate is the most suitable one. [13]



# **Bibliography**

[1] Joseph, Andrew M, et al. "Ethical Perspectives of Therapeutic Human Genome Editing From Multiple and Diverse Viewpoints: A Scoping Review." Cureus, U.S. National Library of Medicine, 27 Nov. 2022, <u>www.ncbi.nlm.nih.gov/pmc/articles/PMC9793437/</u>. Accessed 04 Mar. 2024.

[2] Redman, Melody, et al. "What Is CRISPR/Cas9?" Archives of Disease in Childhood.
 Education and Practice Edition, U.S. National Library of Medicine, 1 Aug. 2016,
 www.ncbi.nlm.nih.gov/pmc/articles/PMC4975809/#:~:text=CRISPR%2FCas9%20is%20a
 %20gene,genome%20(see%20figure%201). Accessed 04 Mar. 2024.

[3] Joseph, Andrew M, et al. "Ethical Perspectives of Therapeutic Human Genome Editing From Multiple and Diverse Viewpoints: A Scoping Review." Cureus, U.S. National Library of Medicine, 27 Nov. 2022, <u>www.ncbi.nlm.nih.gov/pmc/articles/PMC9793437/</u>. Accessed 04 Mar. 2024.

[4] Basinger, David. "God and Human Genetic Engineering." Cambridge Core, Cambridge University Press,

www.cambridge.org/core/elements/abs/god-and-human-genetic-engineering/0CF5C8768F2 F8091C4A5BB773EACEE16. Accessed 04 Mar. 2024.

[5] "Genetic Engineering." Genome.Gov,www.genome.gov/genetics-glossary/Genetic-Engineering. Accessed 04 Mar. 2024.



[6] "Recombinant DNA Technology." Genome.Gov,

www.genome.gov/genetics-glossary/Recombinant-DNA-Technology#:~:text=Definition&te xt=Recombinant%20DNA%20technology%20involves%20using.create%20genes%20with %20new%20functions. Accessed 04 Mar. 2024.

[7] Shah, Parth. "Informed Consent." StatPearls [Internet]., U.S. National Library of Medicine, 5 June 2023,

www.ncbi.nlm.nih.gov/books/NBK430827/#:~:text=Informed%20consent%20is%20the%2
Oprocess.undergo%20the%20procedure%20or%20intervention. Accessed 04 Mar. 2024.

[8] "NCI Dictionary of Cancer Terms." National Cancer Institute, <u>www.cancer.gov/publications/dictionaries/cancer-terms/def/off-target-effect</u>. Accessed 04 Mar. 2024.

[9] "What Are Genetic Therapies?" National Heart Lung and Blood Institute, U.S. Department of Health and Human Services,

www.nhlbi.nih.gov/health/genetic-therapies#:~:text=Genetic%20therapies%20are%20appro aches%20that,new%20gene%20to%20affected%20cells. Accessed 04 Mar. 2024.

[10] Institute of Medicine (US) Committee to Study Decision Making. "Asilomar and Recombinant DNA: The End of the Beginning." Biomedical Politics., U.S. National Library of Medicine, 1991, <u>www.ncbi.nlm.nih.gov/books/NBK234217/</u>. Accessed 04 Mar. 2024.

[11] "Full Stack Genome Engineering." Synthego, www.synthego.com/learn/genome-engineering-history. Accessed 04 Mar. 2024.

[12] International Patenting Trends in Biotechnology: Genetic Engineering, <u>www.nsf.gov/statistics//issuebrf/sib99351.htm</u>. Accessed 04 Mar. 2024.



[13] "The Problem With Genetic Engineering." Green America, greenamerica.org/gmo-inside. Accessed 04 Mar. 2024.