


Forum: International Bioethics Committee

Topic: Assessing the Ethical and Governance Challenges of CRISPR Gene-editing in China

Chair

# Introduction

Gene-editing technology is changing the future of medicine by making it possible to alter DNA accurately. Among these technologies is Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR), which is a technology that scientists use to modify the DNA of living organisms. It was developed by adapting a natural defence system found in bacteria that researchers modified to accurately edit DNA in plants, animals, and humans. CRISPR is considered a revolutionary technology because it allows scientists to edit DNA in an easy way. It has opened new possibilities for treating genetic disorders, advancing medical research and developing more cures for diseases because it can directly alter DNA sequences which makes it highly versatile and precise.

CRISPR is beneficial because it is a powerful gene-editing technology that is modernizing biomedical research and clinical medicine. It allows scientists to rewrite the genetic code of many organisms, which helps with treating genetic disorders, diagnosing, and curing some types of diseases. However it has several limitations and ethical concerns, particularly regarding human germline editing.

Despite its potential, the use of CRISPR in human germline editing has become a controversial issue in China, where a Chinese scientist, He Jiankui used a technique called CRISPR-CAS9 to create the first genetically modified babies using two twin girls. In this experiment, he edited one of their genes to make them resistant to a HIV infection. This was controversial because it violated Chinese ethical guidelines where it is prohibited to implant genetically modified embryos into a woman, it was also not known if the babies needed the treatment. Scientists later found that the gene-editing was not fully successful which could cause long term health effects such as genetic mutations in the twin girls.

This issue connects to this year's AMMUN theme "Moderating Morality", because it requires governments to balance scientific innovation with ethical responsibility, because while CRISPR gene-editing has so much potential in improving healthcare it also raises many concerns about editing human embryos, and the possibility of non-medical enhancements such as "designer babies".

# Definition of Key Terms

## Bioethics

Bioethics is the study of the moral and ethical questions that arise from developments in biology, medicine and biotechnology. It examines how scientific advancements should be used responsibly by considering their impact on individuals, society and the environment, and guides ethical design making in these fields.

## Gene-editing

The ability to make specific changes in the DNA sequence of a living organism by adding, removing or replacing specific genetic sequences through different technologies such as CRISPR to modify genetic composition.

## DNA (deoxyribonucleic acid)

DNA is the molecule that carries genetic information for the development and function of an organism.

## Genome

The genome is the complete set of DNA in a living organism. In humans, most of the genome is in the nucleus. And a small amount is found in the mitochondria. It contains the genetic information needed for an organism to develop function and reproduce.

## Human Germline editing

The process of altering the DNA of human reproductive cells and embryos, the genetic modifications made to the germline are permanent and can be passed on to future generations.

## CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats)

Clustered regularly interspaced short palindromic repeats is a gene-editing

technology scientists use to make changes to the DNA of living organisms it was adapted for laboratory use from the immune system in bacteria.

### CRISPR-Cas 9

CRISPR-Cas9 is a genome editing tool that enables geneticists and medical researchers to edit parts of a genome by removing, adding or altering sections of the DNA sequence. It works by using an enzyme called Cas9 to cut both strands of the DNA at a specific location which allows genetic material to be inserted, removed or modified. The cell then repairs the DNA resulting in the desired genetic change.

### Genetic mutation

A genetic mutation is a change in the DNA sequence of an organism. Mutations occur when DNA is copied incorrectly or damaged. They can cause genetic disorders or diseases.

### Designer babies

A designer baby is a baby whose embryo has been genetically modified to achieve specific characteristics. This can be achieved through genetic techniques such as CRISPR.

## General Overview

### The Origins and Development of CRISPR

Gene-editing has been around for decades; however, earlier techniques were often complex, time consuming, expensive and less precise than modern methods like CRISPR. Before CRISPR was discovered, scientists noticed unusual, repeated DNA sequences in many different bacteria but did not understand them. Francisco Mojica, an associate professor of microbiology realised that they were all a part of the same biological system and not just random. This led scientists to identify the system as CRISPR and understand that it protects bacteria from viruses.

Then a French scientist named Alexandr Bolotin identified an unusual CRISPR DNA sequence. This led him and other scientists to the discovery of a new protein related to CRISPR that could cut DNA which is now known as Cas9. In 2007, scientists found proof of CRISPR's work as a defence system that protects bacteria from viruses, they also found that bacteria store small pieces of viral DNA in CRISPR to help fight future infections. Most importantly they found that Cas9 is the main part of destroying viral DNA.

After that scientists started to discover that CRISPR could be used as a gene-editing tool. Scientists demonstrated that Cas9 could be reprogrammed to cut different DNA systems. After that, scientists successfully developed CRISPR-Cas9 for genome editing in human and mouse cells.

## Applications of CRISPR in Gene-Editing

CRISPR-Cas9 has become one of the most efficient gene-editing tool in the biotechnology scientific community. Many diseases are accompanied by changes of gene expression in the body, especially the diseases caused by genetic mutations.

One of the most significant applications of this technology is in human therapeutics and medicine, making it one of the most significant advances in modern biotechnology. One of its primary uses is treating genetic disorders by correcting disease-causing mutations in DNA. For example, CRISPR has the potential to treat inherited conditions such as sickle cell disease and cystic fibrosis. Scientists also use CRISPR to modify T cells, enhancing the immune system's ability to recognise and destroy cancer cells. In addition, CRISPR can repair certain DNA mutations, offering new possibilities for treating previously incurable diseases.

Beyond medicine, thus technology also plays a vital role in environmental biology and biotechnology. It helps in gene drives by forcing a specific genetic trait such as infertility through generations. This is used a lot in mosquitoes that transmit malaria. CRISPR can also edit microorganisms to produce things like industrial enzymes more efficiently.

Another major application of CRISPR is in research and discovery of new medicines. Scientists use CRISPR to perform screenings to disable genes and discover their functions in the body. CRISPR is also heavily used to build animal or cell models to act as human diseases to be used as testing platforms for medicines.

## Human Germline Gene-Editing

Human germline editing is the process of altering the DNA of reproductive cells or embryos. These cells dictate the genetics of the offspring, so the modified DNA will be passed down to future generations.

This is different from somatic editing which is used to modify the DNA in non-reproductive cells to cure diseases. The key differences are somatic cell editing is not passed down to future generations, and the changes are only for one individual, it is used in clinical treatments and is used to treat certain types of cancer. However, germline gene-editing targets sperm and egg cells, and is passed down to future generations. Its main purpose is to prevent transmission of genetic diseases to future generations in their family; however, it is highly controversial worldwide.

Germline editing is a permanent change because of these crucial points. Techniques like CRISPR-Cas9 permanently cut and rewrite the genetic sequence of the target DNA so the newly introduced genetic code becomes a permanent part of the cell. Germline cells are present at the earliest stages of human development. As an embryo grows, these modified cells divide and differentiate to form the body's tissues, including the future reproductive cells. Because the edited DNA becomes embedded in the chromosomes of these cells, the genetic changes are permanent and can be passed on to future generations. As a result, any unintended changes made during the editing process cannot be easily reversed.

The only known case where CRISPR was used to create gene-edited children was in 2018. This was done by Chinese Professor of Science and technology He Jiankui. His goal was to disable the CCR5 gene and he hoped by changing that gene the children would be resistant to HIV.

## Scientific Challenges and Risks

There are many challenges and risks that come with using CRISPR as a gene-editing tool. The most important ones are unintended genetic alterations. Which is that CRISPR-Cas9 can unintentionally cut DNA signals which disrupts healthy genes or cause chromosome rearrangements. Recent studies show that CRISPR can cause unintended genetic changes and when editing embryos not all cells can receive the intended edit, resulting in unpredictable long-term traits.

Another challenge is the difficulty of delivering CRISPR into target cells and managing the body's immune response. Getting CRISPR to the correct cells or organs safely without getting destroyed by the body is extremely challenging. Also, because the Cas9 protein is taken from bacteria, it can trigger unwanted responses from the immune system. There are also many biological uncertainties. For example, the understanding of gene-editing is still incomplete so editing one gene could cause an unexpected trigger. There is also the chance of off-target modifications that could cause long term effects on a patient such as a higher cancer risk, the death of cells and disrupting the function of some genes.

## Ethical Challenges

CRISPR presents several ethical challenges, particularly surrounding human germline modification, as changes made to reproductive cells can affect future generations. It also raises concerns about socioeconomic inequalities, the possibility of creating “designer babies,” and the risk of unintended genetic mutations occurring during the editing process.

The first ethical concern is modifying reproductive cells in humans, which results in the genetic changes being passed down to future generations. The ethical challenge here is that future generations cannot consent these alterations. Some argue that it could remove many diseases that are passed down by genetics. These changes could cause irreversible mutations and long-term consequences.

Another concern is that even with the advanced techniques we have today, CRISPR can cut unintended parts of the genome, leading to off target effects. Target effects are long term biological consequences that happen when a gene-editing tool interacts with molecules, proteins, or DNA sites other than the ones it was meant to affect. The long-term psychological impacts of these consequences remain unknown raising safety and moral concerns.

The global scientific community faces challenges due to differing ethical standards across countries, which has sparked debates about how to establish, monitor, and implement ethical guidelines for CRISPR technology.

## Governance and Regulatory Challenges of CRISPR

CRISPR faces major global differences in which countries disagree on many different things, mainly safety concerns, and because of the low- cost and high accessibility of CRISPR-Cas 9, it creates several governance challenges.

Different regions regulate gene-editing differently. For example, the United States department of agriculture does not have strict regulations for gene edited crops, while in the European Union there are very strict regulations for gene edited plants and animals. This creates barriers for international trade.

There are also many concerns in human germline and enhancement. Somatic cell editing, which is treating non inheritable diseases is widely accepted and regulated to ensure safety. On the other hand, germline editing is highly controversial since the creation of "designer babies" and socio-economic enhancements worry ethicists and regulators.

Because CRISPR is cheaper and easier to use than older gene-editing technologies, it has raised concerns about it being used outside traditional research laboratories. Gene-editing conducted by non-biologists or inexperienced people remain a major concern.

There have also been various disputes regarding intellectual property and legal rights, which make commercial access and global equity more difficult. These challenges can result in licensing issues and raise concerns that less economically developed regions

may not be able to afford or access agricultural and medical advancements if these issues continue.

## Major Parties Involved

### China

China is one of the most relevant parties involved because it is one of the countries that invests most heavily in CRISPR and one of the leading countries in using CRISPR in clinical trials. Also, the scientist He Jiankui the person who created the first gene edited babies using CRISPR-Cas9 is Chinese and conducted the experiment in China. The experiment was conducted without any approval and broke several ethical laws. After this China strengthened their regulations and introduced stricter ethical procedures for human genome editing research. This puts China in the middle of most ethical debates regarding CRISPR.

### World health Organization (WHO)

The World Health Organization (WHO) is a global organisation responsible for helping ensure that gene-editing technologies, including CRISPR, are used safely and ethically. After the controversy surrounding the first gene-edited babies in China in 2018, the WHO created an Expert Advisory Committee on human genome editing in 2019 to develop recommendations for the responsible use of genome-editing technologies. In 2021, the WHO published Human Genome Editing: A Framework for Governance, which helps countries understand how to regulate and manage genome-editing technologies.

### United Nations Educational, Scientific and Cultural Organization (UNESCO)

UNESCO helps promote the ethical and responsible use of CRISPR, by emphasizing the importance that scientific innovations such as genome editing must respect human rights. After the first genetically modified babies were born UNESCO called for stronger international regulations and greater transparency in scientific research to prevent similar cases from occurring. UNESCO is also relevant through its Universal declaration of the

human genome and human rights and its creation of the International Bioethics Committee (IBC).

### International Commission on the Clinical use of Human Germline Genome editing

The international commission on the clinical use of human editing was established by the US national academies and the UK royal society it has developed recommendations of where human germline genome editing should be considered for clinical use. Many governments use their reports as references for policies regarding genome-editing.

### The United States of America

He Jiankui was the scientist who created the first gene edited babies was a researcher in universities located in the United States such as Stanford. Moreover, many CRISPR scientists in the United States spoke about the experiment and strongly condemned it. The government of the US also prohibits using federal funds for research to create gene edited babies and has strict oversight for it.

### The United Kingdom

The United Kingdom has one of the strongest regulations for embryo research. In the UK Scientists are only allowed to perform gene-editing on embryos for research and implanting gene edited embryos is not allowed.

## Timeline of events

| Date | Event |
|---|---|
| 1987 | Japanese scientists first discovered unusual, repeated DNA sequences in bacteria. |
| 2012 / 6/ 28 | Two scientists Jennifer Doudna and Emmanuelle Chapentier published CRISPR-Cas 9 as a technology that could be |

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|---|---|
| | programmed to cut DNA in specific locations which introduced CRISPR as a gene-editing tool |
| 2015 / 4/ 18 | Chinese scientists became the world's first scientists to use CRISPR where they used it to edit non-viable human embryos. |
| 2018 / 11/ 25 | He Jiankui had edited the CCR5 gene in two twin girls making them the world's first gene edited babies. |
| 2019/ 1/ 21 | Chinese authorities concluded their investigation where they found that He Jiankui violated national regulations and ethical standards. |
| 2019/ 12/ 30 | He Jiankui was sentenced to three years in prison and fined 3 million Chinese yuan for illegal medical practices. |

## Attempts to Solve the Issue

### Universal Declaration on the Human Genome and Human Rights. (11 November 1997)(UNESCO General Conference Resolution 29 C/Res.16)

This resolution was adopted by UNESCO's General Conference in 1997 to establish the Universal Declaration on the Human Genome and Human Rights. It asked Member States to ensure that advances in genetics and biotechnology respect human rights and human dignity while encouraging international cooperation and ethical oversight of genetic research. The resolution supported scientific technologies, such as CRISPR gene-editing, and emphasised that they should benefit humanity without compromising ethical principles. This helped establish the first international ethical framework for human genome research and editing.

### Universal Declaration on Bioethics and Human Rights (2005/10/19)(UNESCO General Conference Resolution 33 C/24)

This resolution was adopted by UNESCO's General Conference in 2005 to establish the Universal Declaration on Bioethics and Human Rights. It called on Member States to promote ethical standards in medicine, life sciences, and emerging technologies, ensuring that scientific developments respect human dignity, consent, equality, and social responsibility. This encouraged governments to strengthen ethical oversight and international cooperation when regulating new technologies, including genome editing. This provided a comprehensive global framework for the ethical governance of biotechnology.

## Possible Solutions

One possible solution to the topic of ethical and governance challenges surrounding CRISPR gene-editing in China, would be to create a list of serious inheritable diseases, and germline editing would only be allowed or considered for diseases on that list and when no alternative effective treatment is possible or exists. The list should be updated every few years by medical experts from around the world.

This solution would prevent the use of CRISPR, for enhancement purposes like changing eye colours or hair colours, while still leaving room for research that could prevent severe diseases. Countries that contain a lot of experts in the field of biotechnology would contribute scientists to help create the list which will ensure that the list is created based on medical needs.

Another possible solution would be to establish a licencing system for all research involving germline gene-editing. Because many researchers take advantage of countries that have laws with weaker oversight. Any scientist or institution wishing to conduct germline gene-editing research would need to obtain a license issued through a United Nations body such as the WHO or UNESCO. The licencing process would require ethical reviews, proof of scientific necessity and compliance with international safety standards before research

begins. Researchers who violate any requirement would have their licence revoked, preventing them from conducting any future research

The case of the world's first CRISPR gene-edited babies in China, made it clear that national regulations alone could not prevent unethical experiments. An international licencing system strengthens accountability by ensuring that scientists cannot move their research to countries with less strict regulations, it will also promote ethical standards across all countries conducting human gene-editing research.

## Guiding Questions

1. How does CRISPR affect or benefit your country?
2. Does your country currently conduct or support research involving CRISPR?
3. What laws does your country have regarding CRISPR germline gene-editing?
4. Has your country ever publicly supported or criticized China's use of CRISPR technology and for what reasons?
5. Is your country a member of any international organisations or agreements that influence the governance of CRISPR gene-editing technologies?
6. What is CRISPR gene-editing and what ethical concerns does it raise while being used on humans?
7. Why did the gene-editing of two twin baby girls in China become a major international and ethical controversy?
8. What are the main governance challenges associated with CRISPR gene-editing technology?
9. Which international organizations play the largest role in developing ethical standards for human gene-editing and what are the recommendations they made?
10. How could inconsistent laws between countries affect the safe and ethical use of CRISPR technology?

11. What are some of the benefits of CRISPR gene-editing for treating genetic diseases and how could these benefits be balanced with ethical concerns?

# Appendix

- What is CRISPR? (National Human Genome Research Institute - NIH): **https://www.genome.gov/genetics-glossary/CRISPR**
- WHO Recommendations on Human Genome Editing (World Health Organization):**https://www.who.int/publications/i/item/9789240030060**
- UNESCO: Human Genome and Human Rights: **https://www.unesco.org/en/ethics-science-technology/human-genome-and-human-rights**
- Genome Editing and Human Reproduction: Social and Ethical Issues (Nuffield Council on Bioethics):**https://www.nuffieldbioethics.org/publication/genome-editing-and-human-reproduction-social-and-ethical-issues**
- China Becomes a World Leader in Genome Editing (Science): **https://www.science.org/content/article/its-crispr-revolution-china-becomes-world-leader-genome-editing**
- Governance and Regulation of Human Genome Editing (PubMed Central):**https://pmc.ncbi.nlm.nih.gov/articles/PMC9377665/**
- CRISPR Timeline (Broad Institute): **https://www.broadinstitute.org/what-broad/areas-focus/project-spotlight/crispr-timeline**
- World's First Patient Treated with Personalized CRISPR Gene-Editing Therapy (Children's Hospital of Philadelphia): **https://www.chop.edu/news/worlds-first-patient-treated-personalized-crispr-gene-editing-therapy-childrens-hospital**

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