

# Research Report

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Human Rights Council

Implementing protocols regarding the development  
and application of gene therapy

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<b>Forum</b>	Human Rights Council
<b>Issue:</b>	Implementing protocols regarding the development and application of gene therapy
<b>Student Officer:</b>	Luis Eduardo Rodriguez
<b>Position:</b>	Deputy President

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## Introduction

Aldous Huxley warns that “Science is dangerous; we have to keep it most carefully chained and muzzled” (Brave New World, page 231). The statement in this novel is used to explain that science does not always contribute to human happiness and well-being. Scientific development can disturb social stability, as well as generate inequality and other socioeconomic troubles. Like in Brave New World, modern technology is approaching fields of knowledge that are potentially dangerous for the basic concepts of human nature and social order. The development of gene therapy, cloning and other advancements in medical fields of science, combined with the precedents of ethnic cleansing during wars and other conflicts, have sparked debate on how to administer new knowledge and technology.

Yet the world that Huxley presents in his novel is a place where war, poverty and disease have been forgotten. Humanity is a big entity that is prosperous and forward thinking, goals that the UN and other bodies seek to achieve. This is why the fear towards groundbreaking scientific processes can stiffen progress in other fields such as political integration and social stability. It is therefore up to discuss whether the past attempts to regulate the new gene therapy technologies were called for, or whether we can find a more enlightened way of dealing with these new challenges.

The discussion regarding gene therapy had a peak in the 1990's. The problems surged with the mapping of the Human Genome by the United States of America. Methods such as in vitro fertilization, contraceptive methods and gene therapy are highly controversial subjects that are often criticized by conservative or religious political and social groups. Countries around the world have established their own regulations that control the implementation of the different techniques of gene therapy, the boundaries for the research and the ethical frame in which these will proceed.

Gene therapy nowadays is starting to resurface, and morals are loosening up. Even though the debate on how research will pursue and which ethical guidelines it will follow continues, most pressing issues have already been solved either by the UNESCO or other national or supranational organisations, like the FDA or the Council of Europe.

Questions on whether enhancement of the Human Genome is moral, or if only medical reparations of the human DNA heritage should be pursued, are still in open debate. Around the world, people seem to be opening up for enhancement techniques, but conservative movements are also growing stronger and louder. Next to the social development, the breakthroughs in gene therapy are still small due to the tight regulations and fear towards the manipulation of the human DNA. Racism and other ways of expressing hatred could be taken to unthinkable extremes, but the benefits also have the potential revolutionary impact.

Taking Huxley's idea of a controlled science, one sees it is up to policy makers and health institutions to debate whether we will restrain development in fear of the problems that may arouse, or if mankind will take the risk of a new revolution in science.

## Definition of Key Terms

### Gene Therapy

Gene therapy is a procedure that consists of the deliberate changing of the DNA sequence of cells, or even entire organisms, by replacing a gene/gene sequences with the desired sequence or tissue through insertion methods.

### Germline Therapy

Germline genetic therapy consists of changing the genetic structure of cells through the injection of a third 'germ-like' body in the cells, so that genetic sequences or whole new DNA is created. For this therapy to be interpreted as germline therapy, the mutation has to occur within the reproductive cells, which would carry on the mutation to future generations. Germline therapy is widely controversial, and forbidden in some countries like Australia. This is because germline therapy has the potential to alter the human genome and hence change the nature of mankind.



## Somatic Therapy

Somatic gene therapy is the modification of 'differentiated cells' or cells that do not influence the reproductive system, meaning that they do not transfer their mutation to the next generation. This type of gene therapy is widely accepted and used nowadays, since it does not pose a threat to the changing of the Human Genome.

## Human Genome

The Human Genome is something that can be compared to the building instructions of humans. These are unique sequences of DNA that are found in 23 different chromosomes. The Human Genome is made up of billions of amino acid combinations. While each human is unique, the basic structure of the Human Genome is the same for all, which explains why all humans are humans.

The genome structure of other species varies and gives them their different characteristics, just as the smaller variations in our individual genome makes each and everyone of us unique. The Human Genome Project began by initiative of the USA in 1984 and was declared finished in 2003.

## General Overview

Gene therapy has been debated in the late 90's and early 2000's. In this time, most developed countries established measures to regulate and administrate gene therapy. The guidelines established by these governments and institutions dictate that gene therapy should be used only for the improvement and healing of human beings. This means that somatic treatments of genetical illnesses such as cancer are more than welcome, for they cure the sick and improve the living conditions of those who need care.

Some institutions like the Catholic Church officially oppose most of the concepts relating to gene therapy; yet they see the advantages for the treatment of the sick. In 2008 the Vatican issued a document stating "a human is sacred from conception, and no form of experimentation on embryos or use of embryonic stem cells is at all acceptable in any form" (Dignitas Personæ 1). Similar to the Catholic belief, the Islam doesn't oppose gene therapy as long as the methods do not transgress Allah's work. Furthermore, even though certain procedures may not comply with the Shari'ah, they are allowed in cases of extreme necessity, for example to save a patient's life.

Overall the usage of gene therapy has to comply with the Declaration of Helsinki, which dictates points on human experimentation. Some of these are the right to an informed decision or the right to self-determination. The subject's welfare must also stand above the interests of science and society.

### **Somatic Therapy**

While germline therapy remains forbidden in Australia, Canada, Germany, Israel, Switzerland, and the Netherlands, somatic therapy is experiencing stable development in the fields of medicine. In the US alone, over 600 clinics will start using somatic therapies to treat severe genetic disorders like immunodeficiencies or cystic fibrosis.

Nevertheless, success in these kinds of therapies is varied and very scarce studies are nowadays in advanced stages. Sickneses like ADA (Adenosine Deminase Deficiency, a sickness that affects the immune system) can only be treated with somatic gene therapy, showing at hand of this example that gene therapy is still a relevant component of modern medicine that might be worth pursuing.

## **Major Parties Involved and Their Views**

### **UNESCO**

UNESCO published a paper entitled 'Report for Human Gene Therapy' that showcases their point of view. This report is a liberal international policy frame that allows the usage of somatic gene therapy both for enhancement and medical treatment, and also conceives the idea of the usage of germline therapy, not forbidding it. This Report has been often described as 'liberal' in comparison to those policies implemented by some states or the European Union.

### **World Health Organization (WHO)**

The WHO points out that since the dawn of gene therapy, the traditional concerns about safety, confidentiality, discrimination etc. aside, gene therapy poses a new beginning for the field of medicine and science. Some of these new key aspects are for instance the susceptibility and probability that medical care will encounter when pursuing the path of gene therapy.

### **National Institute of Health (NIH) and the Federal Food and Drugs Agency (FDA)**

The NIH and FDA are the bodies that oversee gene therapy in the United States. Even though there is no federal legislation on the matter, the agencies have established their own measures and parameters to administrate the development of gene therapy.

The human germline therapy is overseen by the NIH's branch RAC (Recombinant DNA Advisory Committee). The development of germline therapy is not to be funded with federal funds and is also liable to state legislation, which might mean limitations and banning of the research.

The FDA and NIH are the institutions that possess all crucial information in regards to germline therapy. They oversee the developments and commercialization of said procedure.

## Timeline of Events

The developments in the timeline are seen from the perspective of the United States due to the fast response and relevance of this country for the matter. The events in the timeline should show the quick action-reaction relationship between the development of science and of regulation.

Date	Event
1969 - 1970	Paul Berg and Peter Lobban discover how to create and manipulate DNA and how to use these for the manipulation of genes
1971	First concerns in regards to gene therapy
1972	First publishing of the methods for the creation and manipulation of DNA
1972 - 1973	First conferences begin in regard to the new technologies being developed
1976	The National Institute of Health (NHI) establishes the first guidelines in gene therapy
1980	First experiments of transfer on humans led by American scientists in Italy and Israel, later censored and barred by the NIH
14th Sep 1990	First somatic gene transfer on humans



24th Dec 1994	UNESCO Report on Human Gene Therapy
2000	French doctors accomplish the first complete germline gene therapy on 10 'bubble boy' syndrome patients
2001	First germline gene therapy is used - 30 children are born as a result
2003	The FDA temporarily bans further research on germline gene therapy

## UN involvement, Relevant Resolutions, Treaties and Events

In 1994 UNESCO presented a report on gene therapy. This report is a liberal framing of the ethics of gene therapy. It is based on surveys and other means of data recombinations. The UNESCO proceeded to create a guideline for the approach towards gene therapy. The document established clear boundaries for the research, implementation and commercialization of therapeutic gene methods.

The UNESCO report can be summarized through the following points. Firstly, somatic gene therapy is acceptable and can be used to treat all types of diseases. Somatic gene enhancement (to improve qualities in a person) should also not be illegal.

Furthermore, germline gene therapy should also not be illegal, yet germline enhancement should not be pursued. The latter takes into account the dangers this would pose to society and human nature.

## Evaluation of Previous Attempts to Resolve the Issue

The surge of new technology and knowledge by the end of the 20th century inspired a series of new policies in regards to gene therapy. Administrations around the world analyzed the risks and consequences of the implementation of gene therapy, and before much work could be developed rigid framework for the development of the new technology was formed. Such policies, like the prohibition of germline gene therapy, limited the potential of what might've been the next scientific and even evolutionary revolution. The arguments were based on the fear of the ending of humans as we know it, creating super humans or creating other humanoid beings that would end the actual social paradigm. This course of action would have sparked waves of racism and segregation like never before. The world,



perhaps still bearing the images of the holocaust in mind, decided to opt out of this new science that has the potential to give humans godlike powers in the field of biology.

The choice to put the break on gene therapy created much controversy. The public opinion turned the subject into something rather negative, but with rising problems such as new diseases, overpopulation and poverty it's important to expand our frontiers by understanding gene therapy more than we do nowadays. Many questions were answered by the mapping of the Human Genome, yet many keep rising or remain unanswered.

## Possible Solutions

The comprehension of the Human Genome and the beginning of gene therapy seems to a rather risky and dangerous enterprise for mankind to approach. There is great fear of changing human nature as we know it, but some believe it is up to us to take our evolution into our own hands. This is why debating on the matter is needed. Possible liberalization of policies in regard to germline therapy, like the legalization of this field and maybe the cooperation of the states with scientists willing to pursue it, are possible measures to encourage the progress in the field of gene therapy. Awareness and the demystification of the development of gene therapy would also aid the support of the general public and would also permeate the religious and moral opposers.

The UN presents the best platform to develop dialogue and scientific research in the field of gene therapy. Almost all countries are represented here, and funds are available for any eventual projects. Organisations like the WHO or the UNESCO should bring all nations together to pursue more investigation and more regulation in the field of gene therapy. Transparency and international collaboration are some of the United Nations' top priorities; thinking of working within its margins seems like a good way to start.

Research in such a sensitive field should be well monitored, both to allow progress but also ensure safety. This task needs to be agreed with a consensus, since the magnitude of gene therapy, especially germline gene therapy, affects humanity as a whole; any decisions made will have global consequences. A way to achieve this is by setting up congresses, think tanks and regulating agencies, all overseen by international liaisons and treaties between nations.



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## Appendix or Appendices

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The declaration of Helsinki

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