Criminal Protection of Human Genome "Human Gene Editing as a Model"

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Abstract

Lawful protection of the human gene conceded a moral concern regarding the future of existence human. After the discovery of the human genetic map, scientific experiments and research related to the human gene increased, negative applications of genetic engineering in particular that violate essential human rights, the right to human dignity to be specific. These practices represent actual challenges to the existence and diversity of current and future generations. Therefore, the presence of legal rules at the domestic and global levels is an absolute necessity to prohibit these threats and determine civil and criminal accountability for those who infringe any laws related to this issue.

Keywords: Human Genome, Human Gene Editing, Legal Protection, Human Genome Crimes**.**

الحماية الجنائية للجينوم البشري "التعديل الجيني البشري إنموذجاً"

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الملخص

الحماية القانونية للجينوم البشري تعد قضية أخلاقية تتعلق بمستقبل الوجود البشري، بعد الكشف عن الخريطة الجينية البشرية، ازدادت التجارب العلمية والبحوث المتعلقة بالجينوم البشري، وخاصة التطبيقات السلبية للهندسة الوراثية التي تنتهك حقوق الإنسان الاساسية، لا سيما الحق في كرامة الانسان. أن هذه الممارسات تعد تحديات حقيقية لوجود وتنوع أجيال الحاضر والمستقبل. لذلك ، فإن وجود قواعد قانونية على المستويين الوطني والدولي ضرورة مطلقة لحظر هذه التهديدات وتحديد المسؤولية المدنية والجنائية لمن ينتهك هذه القواعد.

الكلمات المفتاحية: الجينوم البشري- تعديل الجينوم البشري- الحماية القانونية- جرائم الجينوم البشري.

Introduction

Human gene editing is forbidden by rulings, regulations and guidelines in most states. Nevertheless, the first criminal case involving "genome-edited" children in China was condemned in 201٨. Gene editing on healthy human embryos may lead to irreversible mutations and serious consequences for the inheritance of future generations, while their long-term safety is unpredictable. [1]

Purpose: A complete set of laws and regulations should be formulated along with strategies to punish gene editing acts and preclude similar adverse measures in the future. As well as, binding mechanisms between different countries should be built and implemented. The international and regional collaborative network must be strengthened in order to improve global registration and monitoring of human gene editing technologies and research.

Research Objectives: The importance of the subject lies in its seriousness, its novelty and the controversy that has arisen around the technology of modifying the human genome. There is a fear that this technology will not be limited to treat and prevent diseases, specifically after the use of CRISPR-Cas 9 technology in 2018 in China, and the announcement of the birth of the first two genetically modified daughters in the world. In addition, the current study will help to identify the legislative position of the countries regarding this technology.[2]- [3]

Research Methods: The present study relied on the descriptive analytical comparative approach by studying legal materials in various countries.

Research Question: What is the human genome, its forms and components? What is the crime of human gene editing? How did countries confront the technology of human gene editing?

Therefore, a direct action must be taken to use this technology without violating laws, regulations and instructions in a way that does not affect humankind liberty and dignity.

The research question will be answered through the following outline:

The First Topic: The Concept of Human Genome. The Second Topic: The Nature of the Human Genome. The Third Topic: Forms of Assault on Human Genome.

The First Topic
The Concept of Human Genome.

The human genome is one of the important matters that have captured the attention of biologists and jurists alike. Due to many repercussions it imposes and necessities the existence of a connection between genetics and the law. [4].

The following section will illuminate the concept of the human genome as follows:

The First Requirement
History of the Human Genome.

After Mendel's first experiments in the nineteenth century, this science was not adopted until the twentieth. The scientists began to determine where genetic characteristics are based and it is identified that in all living species there are elements of chromosomes. Genes are found in the chromosomes. In the second half of the twentieth era, medical and biological sciences topped the forefront of experimental sciences, especially the matter of the human genome. It has received widespread attention from both specialized research centers and public opinion due to the widespread interest in its legitimacy and the anticipations placed on its positive repercussions for the future.[5] In fact, the actual emergence of the concept of the human genome was associated with a project called the Human Genome Project (HGP). Scientists and researchers were able to uncover human genes through this project. Most of the world's advanced countries in the field of biotechnology participated in this project and exchanged information in order to determine the location of each gene, its function and its relationship to other genes. Also, decipher the genetic code of Jane. This project will help to recognize what type of protein that gene can produce. Based on that, scientists can draw a genetic map that determines the sequence of nitrogenous bases. Each gene consists of a large number of these nitrogenous bases. Approximately, the number of these rules is three thousand

million, distributed among the genes that are found in three twenty-three pairs of chromosomes. [6-7]

The (HGP) is a research project that officially began in 1990. It was scheduled to take a part of 15 years, but technological developments accelerated its work until it was about to be completed years before its scheduled date. Its initial results were announced in 2000, and the final result of the project was announced in 2003. This led to research in areas with more distant goals[8]. The project began in the US as a dual effort between the Department of Energy (DOE) and the National Institutes of Health (NIH). The stated goals of the project were: identifying the approximately 100,000 genes contained in human DNA (scientists have now discovered only about 22,000 genes), determining the sequence of chemical bases that make up human DNA (numbering 3 billion nitrogenous base pairs) and storing this information. They develop databases and tools to analyze data. In addition they study ethical, lawful and communal issues that may result from the project. [9-10].

The second requirements
Definition of Human the Genome and its Forms.

Under this section, definition and the forms of human genes will be addressed.

The First Branch
Definition of the Human Genome.

The human gene is the entire genetic material made up of deoxyribonucleic acid (DNA). The human gene consists of between 20-25 thousand genes located and arranged in the form of twenty-three pairs of chromosomes in the cell nucleus. Gene size and number of genes vary between organisms.[11]

Legally, legislation has neglected to set a specific definition for the human genome and its components due to the newness of the term and the lack of researchers on it. At the level of Arab legislation, Article 1 of the law regarding the use of the Emirati

human genome of 2023 stated that the genome "is all the genetic material in a living organism, including genes that contain all the biological information that is needed to build and sustain an organism." The last and most distinctive counterpart of its kind, the human genetic balance is composed of (46) compact molecules of DNA called chromosomes, in addition to mitochondrial genes.

On an international level, the "Universal Declaration of the Human Genome and Human Rights of 1997" is the first global document in the field of biology. It is also the most important attempt to strike a balance between safeguarding respect for humankind rights and the necessity of preserving freedom of scientific research. It focused on preserving human dignity and respecting genetic diversity as well as defense on the rights of future generations. This declaration is the beginning of convincing the world to take the necessary measures to regulate the relationship between science and moral values. The Declaration proposed standards to control and regulate research in the field of the human genome.[12]

Article 1 stipulates, "The humankind gene represents the fundamentally element for all members of the human family, and it is regarded the basis of humankind dignity and is the inheritance of humanity." Genome has an individual and collective meaning addressed below:

The individual meaning of the genome: it is defined as the sum of the genes for each individual which means the genome of this individual resulting from each of his/ her biological parents. It is known that each individual has its own genetic material, made up of cells containing a set of information genetic or functional hereditary units in which all data necessary for its growth are recorded.[13] The genome contains about 30 to 40 thousand functional genes, which

constitute only about 3% of the total genetic material, as for the rest of the DNA, is called unwanted genes.[14]-[15]

Collective meaning of the human genome: It means "the genetic model of the hereditary material of all human beings" and the human genome is the genetic material for all humans. Sequencing of the human genome has revealed that 99.99% of human DNA sequences are identical from the genome of one individual to another. This similarity determines regardless of membership in a particular culture, race, or geographic region. The common human genome consists of the common genetic characteristics of humans, as it carries the genetic influence from human ancestors. This represents a widely accepted fact, as all human beings are linked by a common history and every human genome bears traces of the first human ancestors.[16]-[17]

In fact, only 0.1% of the small differences in the DNA sequence determine the differences between one individual from another. Therefore, 99.99% of human genes are similar, which is called shared or collective genetics. The remaining percentage is different and distinguishes some individuals from others. Such as eye tone, skin color, or even predisposition to certain diseases.[18]

The second Branch
The Forms of Human Genome.

Basically, the human genome consists of three main components: a gene, a nuclear chromosome and chromosomes.[19]

First: - Gene:

Biologists and biomedical scientists define genes as: the hypothetical and basic units of operation of heredity which is transmitted from parents to children. In addition, it is responsible for creating certain characteristics in individuals who thrive in a particular environment. Gene is regarded as the basic unit of heredity. Biologists liken a "gene" to an atom. The atom represents

the basic unit of matter for chemists, as well as the gene, represents the basic unit of heredity.[20]- [21]

- The function of genes is that it carries special codes of information necessary to build structural proteins for cells and building enzymes for basic biochemical reactions. Meaning that each gene contains a specific set of genetic information and instructions for making a specific protein or peptide.[22]- [23]
- The HGP has helped identify the functions of nearly 24,000 genes. The project revealed a number of genes related to the human species and others related to the human individual.

There are genes that are present in the body of every individual and others that are specific to the bodies of specific individuals. This will address as follow:

1-Human species genes (traditional genes):-

These genes encode proteins or phenotypic genes found in every individual. It has a specific function, which it is form to the general basic structures of the individual; such as organs and cells. These genes may undergo some change in their function, causing an imbalance in the body.[24]

2-Pseudo genes (unconventional genes):-

These genes include non-coding RNA, pseudo genes and ribosomal RNAs:

- Non-coding RNR genes: These are the genes that regulate the work of the coding genes and are responsible for individual and physical characteristics.
- Ribo Transformers: It is a type of RNA, as it can replace DNA like any gene by encoding a protein and it can replace the protein and its works as a receptor. This type regulates certain personality traits in the human genome.

- Pseudogenes: These are macaroni genes, which have a role in the RNA that is synthesized by them and adjust the gene expression to a real gene.[25]-[26]

3- Genes of Individual Human:-

They are post-genetic marks, as they constitute with the genomic design the "third layer" of the genetic information. Most of these markers are chemical reactions that effectively control the type of genes and also give the individual personal characteristics. It is the link between the first and second type of genes. Although "human type genes" have a role in the initial formation of the body, their effect is secondary and integrates with the action of "human type genes" and the influence of the environment."[27]

Second: Deoxyribonucleic Acid (DNA):

Nowadays, DNA is regarded far more than just a molecule. It has become the icon of contemporary biosciences. Considerate its construction and how it performs has essentially altered our universe.[28]. Most of current biology relies seriously on molecular genetics methods. DNA was initially detected by a German biochemist named" K. Frederich Miescher," in 1869. But for several years, scholars did not realize the importance of this molecule. By 1953, "James Watson, Francis Crick, Maurice Wilkins and Rosalind Franklin," figured out the assembly of DNA — a double helix — which they realized could carry biological information." Watson, Crick and Wilkins," were awarded the Nobel Prize in Medicine in 1962" for their discoveries concerning the molecular structure of nucleic acids and its significance for information transfer in living material. [29]. It is defined as the molecule that carries the genetic information essential for the growth and functioning of an organism.[30].

Third: Chromosome:

The chromosome is the structure that contains DNA in the cell and each chromosome is a single tightly coiled strand of DNA. It is very complex structurally. It contains elements that are necessary for operations such as replication. In 1882, Walter Fleming was the first to discover human chromosomes.[31]

There are dual categories of chromosomes. Firstly, is the somatic chromosomes numbered 22, and secondly is the sex chromosomes (X and Y), which control the gender of masculine or feminine. These genes carry all the proteins necessary for life in an organism. These proteins determine - among other things - a person's appearance, height, eye color and so on. As well as how their bodies metabolizes nutrition or battles infection, and occasionally even determines the way he/she behaves.[32]

The Second Topic
The Nature of Legal Protection of the Human Genome.

There is no clear legal system for the human genome that determines the type of control and protection for it, unlike plant and animal genes, which are subjected to international protection under the Convention on Biological Diversity of 1992.[33]-[34]. Jurisprudence has differed regarding the description of the human gene, and two doctrines emerged, the first is the: realistic doctrine, the second is the ideal doctrine.

The First Requirement
Realistic Doctrine.

The jurists of the realist doctrine have unanimously adopted the idea of considering the human gene as a thing, but the difference has emerged among them in justifying this idea. Some jurists believe that the human gene can be likened to something because it is a general common structure between living organisms (plants and animals) that are not human. So, there is no reason to distinguish between them when searching for the legal nature of the human genome.[35] Therefore, if the gene is a common structure among

organisms, then the human gene is regarded as a thing. Others believe that the gene is an element of the human body that can be separated from it. Therefore, it is considered a thing because the moment it is separated from the body, it does not enter into the components of the person such as hair, blood and teeth. According to this doctrine, the human gene is considered movable property owned by a specific person and has a material entity that can be evaluated. As a result of these opinions, the organs of the human body are considered suitable to be the subject of financial rights and can be disposed of and benefited from. This doctrine indicates that the human body after the separation of the soul, is considered a mere thing that is subject to the rule of machines. The French legislature considered the human gene to be a medicine by virtue of its function. It is a human action that leads to changing the original properties of cells in order to achieve a therapeutic goal.[36] The researcher believes that considering the human genome to be one of the things owned by the individual will lead to acknowledging the person's right to dispose of the genome as anything he/she owns even if this leads to a change in the composition of the gene, such as cloning. As a result, it will remain in the area of legal dealing because of its financial nature.

The second Requirement
Ideal Doctrine.

The jurists of this doctrine consider that the human genome (a personal idea) is a part of the human body, and therefore it is subject to the same protection prescribed for humans.[37] This doctrine objected to the idea of considering the genome as a "thing." The genome has a special advantage in that it contains the genetic material of humans.

The idea that the human genome is considered identical among living organisms is unacceptable. Despite this similarity, humans

differ from other living creatures as well as their status differs in terms of rights and duties.[38]

This doctrine believes that the human genome is a part of the human body and therefore is not considered a "thing." Considering the genome a "thing" would give its owners broad powers over it to change, modify and perform operations on it, hence this is unacceptable. This doctrine pointed out that a person is not considered an inalienable property therefore the genome cannot be considered a "thing." [39]

They criticized the consideration that the human gene as a thing simply because it is classified as a drug by virtue of its function. This is because this therapeutic function that the gene achieves in the field of gene therapy does not negate its being as a biological substance. The French legislature in Chapter 10-665, pursuant to Law 05/28/1996 relating to various measures of a health, social and regulatory nature, has classified it as a therapeutic biological substance. This classification makes it subjects to the rules of human medical biology analysis that helps diagnose and treat human diseases. [40] It can be said that the human genome cannot be considered a thing because it contains the genetic information of an individual. However, it does not belong to people because it is one of the elements of the body that can be easily separated from it without causing harm to the person. It can live separately from the body for a long time and as an independent physical entity. Therefore, it needs to be protected nationally and internationally.

The Third Topic
Forms of Assault on Human Genome.

The amazing progress in genetic engineering techniques, as well as the success achieved by genomics, is not without risks and complex issues in the legal, philosophical and ethical aspects. Kathy Hana a health policy consultant and ethicist in Washington says,

“The knowledge we have gained about the human genome can treat cancer and heart disease and cure millions of various diseases. At the same time, we find that misusing it will lead to intolerance and various problems. We must understand this science more deeply in order to be certain that harm will not be caused to others."[41]

The forms of assault on the human genome are different such as **conducting medical tests without obtaining prior approval from the concerned party** which criminalized under Article (226/25 of French penal code that states, Studying a person's genetic characteristics for other medical purposes or scientific research, or studying them for medical purposes or scientific research without obtaining the prior consent of the person in accordance with the provisions of this law in the circumstances stipulated in Article 16-10 of the Civil Code, shall be punished by imprisonment for one year and a fine of 15,000.”

Misuse of genetic information party which is criminalized under Article (226/26) of French penal code that stipulates, “Diverting any information collected about a person from its intended purpose, which is medical or scientific research by studying his genetic characteristics, is punishable by one year’s imprisonment and a fine of 15,000 euros.”

Conducting genetic research on humans without obtaining prior permission from the concerned party that punished under Article (226/27) of French penal code.

Illegally taking a genetic fingerprint to determine identity that punished under Article (226/28) of French penal code. Human gene editing will be addressed as a specific example of the assaults.

The First Requirement
Human Gene Editing (HGGE)

Gene editing is a genetic engineering technique and a way to make precise changes to the DNA of a cell or organism. It can be used to improve, eliminate or even change DNA in the gene. Human

gene modifying techniques can be used on somatic cells (non-heritable), germ line cells (non-reproducible), and germ line cells (reproducible). Changes that occur in the germ line can be transmitted to future generations through heredity.[42]. These changes have been generally and absolutely prohibited at the international level. Editing the ancestral human genome is the subject of intense debate about its potential consequences for offspring and society in general. It may pose greater safety and ethical issues than somatic human gene editing.[43]-[44] A group of researchers supervised by ,"*He Jiankui*," a professor at Southern University of Science and Technology (SUSTech) in Shenzhen, Guangdong Province, China, edited the human genome using CRISPR/Cas9 technology.[45]

Countries differ in imposing the level of legal protection against human gene editing, and it will be explained as follows-:

The First Branch
Constitutional Protection on the Human Gene Editing (HGGE).

Constitutions differ in the category of rights and freedoms it protects. Among these rights is the right to protect generations from human gene editing. In this branch the constitution protection to this right in various countries is going to be illustrated. For instance:

The German Constitution (1949, amended 2014) indicated in Chapter Seven/Article 74 (Affairs relating to joint legislative authority)

1- Legislative authority includes the following areas..."

Paragraph (19) includes the measures to prevent diseases - laws of pharmacy, medicines and medical products. Paragraph (26) contains the procreation with the help of medical means, analyzing or modifying genetic information, and organizing the fertilization of organs, tissues and cells.

The Portuguese Constitution (1976, amended 2005) stated in Article 3, paragraph 3, "The law guarantees the personal dignity and genetic identity of the human being, especially in the case of the

innovation, progress and usage of technologies in technical experiments."

The Constitution of Greece (1975, amended 2008) stated in Article 5, paragraph 5, "Every person has the right to the safeguard of his/her health and genetic singularity. The law determines matters related to the guard of every person from medical and vital interventions."

The Brazilian Constitution (1988, amended 2017) stated in Article 225, "Everyone has the right to a balanced environment, which represents a public good that is used by people and is important for a healthy life. The government and society have the duty to defend and preserve the environment for present and future generations. It is the duty of the government Preserving the diversity and integrity of genetic resources in the country and supervising institutions specialized in genetic research and benefiting from genetic resources."

The Constitution of the Democratic Republic of the Congo (2005, amended 2011) indicated in Article 202, without prejudice to other provisions in the Constitution, that the central authority is exclusively responsible for issuing laws that regulate specific matters (Article 36), Paragraph (M), legislating laws related to artificial insemination of humans and manipulation of genetic information and transplantation of human organs and tissues.

Swiss Constitution (1848, amended 2014), Article 119 stipulates, "Humans must be protected from the misuse of reproductive medicine and genetic technology (paragraph 1)." All forms of cloning or other forms of interference with genetic material or human embryos are not permitted (paragraph 2/a).) It is not permitted to mix or dissolve non-human genetic and reproductive material with human genetic and reproductive material." (Paragraph 2/b).

The Second Branch
Domestic law Protection on the Human Gene Editing (HGGE).

Under this branch the scope of legal protection on genome editing of human in various countries will be addressed as follows:

The Scope of Mexican Law: The, **"Criminal Code of the Federal District (Mexico),"** includes double provisions that criminalize any genetic interference. Article 154 punishes prison of up to 6 years, disqualification or exclusion from workplace or profession for those who influence humankind genetic factor to alter the genotype for purposes unrelated to for instance, the removal or repression of a grave illness or condition. This provision similarly forbids any genetic alterations for illegal purposes. However, "**the Mexican Federal Criminal Code,"** does not provide for criminal accountability for manipulation of humankind genes.[46]

The Scope of China Law: Although China is realized as a world frontrunner in the field of biomedical technologies related to the humankind gene, it has not yet established suitable statute in this field. It prohibits manipulation of the human genome in the form of regulations. For instance:

1- **Medical Practice Act (June 26, 1998),** Article 14 states, "Doctors may not practice their specialized action without obtaining a certificate. Moreover, under Article 26 of the Act, doctors participating in experimental medical treatment must obtain hospital approval and authorization of the patient or his/her family."
2- **Rules for the Administration of Medical Institutions (No. 149 of August 1, 2005),** under Article 25 of the Rules, medical institutions must adhere to the conformable acts, instructions and health technical rules when carrying out medicinal actions. Breach of medical technical rules is equivalent to rule violations and may result in legal responsibility and penalties."

3- **Administrative Measures for the Clinical Application of Medical Technologies (No. 18 of March 16, 2009 and No. 1 of November 1, 2018),** Article 41 of the 2009 Administrative Measures (which was in force at the period *He Jiankui* was directing his experimentation) stipulates that the medicinal institute has no right in the application of health technology that has been forbidden or banned by the Ministry of Health of the People's Republic of China."

However, the existing regulations in China does not forbid the application of such techniques in relation to an adult, particularly to apply gene editing technologies (such as CRISPR technologies) in relative to a mature in China. It is essential to gain the consent of the hospital ethics committee and the patient's agreement (Articles 8 and 9) of **Resolution No. 460 containing "Ethical guidelines in cell research human embryonic stem).**

Due to the effortlessness of such a process, technologies such as,"CRISPR" are applied in China more often than in all other states combined.[47]

Chinese Criminal Law Article 336 "Unlawful Medical Practice," states: "Anyone who performs unlawful birth control, reversal surgery, false birth control surgery, pregnancy termination surgery, or eliminates pregnancy regulator device from the uterus, when the conditions are dangerous." The offender will be penalized to imprisonment for a term not exceeding three years, criminal imprisonment or probation, and may additionally or exclusively be punished to a fine."

Moreover, "Anyone who causes serious damage to the healthiness of sick persons will be punished by imprisonment for a period of no less than three years and not exceeding ten years and a fine. The penalty shall be aggravated to imprisonment for a period of

no less than ten years and a fine whoever causes the death of a patient."

By 2018, the Chinese authorities stopped all of Professor,"*He Jiankui's,"* research activities because it conflicted with Chinese laws and regulations. In 2019, the professor was penalized to 3 years in a penal institution, fined 3 million RMB and excluded from working in the field of assisted reproductive technology for lifetime. (SUSTech) University has fired him. In 2022, he was free from prison

In response to the professor ,"*He Jiankui's,"* crime, in May 2019, the Chinese government arranged gene editing regulations emphasizing that everyone who tampers with the humankind gene through gene modifying methods will be accountable for any associated negative consequences.[48] The," **Civil Code of the People's Republic of China**," was edited in 2020 by adding Article 1009 which stipulated: "Any therapeutic research action related to humankind genes and human embryos shall comply with relevant national laws, administrative regulations and regulations, and shall not damage persons and infringe moral ethics and community interest." The law was promulgated on Jan. 1, 2021.[49]

The draft of the Eleventh Amendment to China's Criminal Law in 2020 listed 3 categories of crimes: illicit exercise of humankind gene modifying, cloning of humankind embryos, and also seriously jeopardizing the safety of humankind genetic resources; with punishments of up to seven years imprisonment and a fine.[50]

The Scope of US Law: The US is considered one of the most productive countries for research in the field of human gene editing. It has strict laws and regulations regarding the use of technology to modify the human genome. These restrictions are part of a complex regulatory and statutory link that concerns humankind embryo

research in overall and alteration of humankind positive genetic lines in specific.[51]

"**HGGE**" is not lawfully banned but numerous obstacles do not allow the introduction of this technology, including:

1- Several**, "National Institutes of Health"** - which are accountable for funding research in America - have specified that they, "will not fund any use of gene-editing techniques in human embryos."

2- The, **"US Food and Drug Administration (FDA),"** has rejected the use of human gene editing (HGGE) for reproductive purposes, and it is unlikely to alteration its strategy in the forthcoming time.

3 - In 2015, Congress added a modification to the **FDA** funding bill through the "**Bill Rider**" (which is a legislative procedure used during the discussion of a bill by adding a legal provision to the bill). Based on this amendment, it will become impossible for the administrative of US **FDA** to consider any application that includes research in which a humankind embryo is deliberately modified or created in order to modify a human genetic genome without obtaining the approval of the US FDA organization.[52]

Implanting genetically modified human embryos is illegal. However, genetically modifying human embryos for research purposes is allowed. These experimentations are still not eligible for public funding.[53].

The Scope of UK Law: Gene editing is not presently accessible to individuals for reproductive purposes. Such actions would be unlawful in various states, as well as the Great Brain. This is a relatively unique science which will involve additional improvement before it can be used clinically. So far, a minor number of research groups in China, the United States and the Great Britain have used gene editing techniques in humankind embryos that were briefly grown in laboratories, outside the human body. These are not used to create children. Additional study is required before it can

determine whether any of the gene editing technologies developed to date will be an effective, safe, and applicable approach in any given conditions. Although it is legal in the Great Brain to produce and usage genome-edited humankind embryos, sperm or ovals in research under strict authorizing circumstances their use in assisted reproduction would be against the law. It would be necessary to change the law, which would require a lengthy legislative process before this would be allowable.[54]

The UK is the first country in the world to explicitly allow Horizontal Gene Transfer (HNGT) (So-Called Mitochondrial Replacement). This technique is one of the techniques of microscopic injection, and the mitochondria are taken from a donor free of genetic diseases to avoid the birth of a child with hereditary diseases such as diabetes and heart disease.[55]

In 2015, the British Parliament authorized the use of "HNGT". It became the first country in the world to publicly challenge global policy regarding reproductive gene editing. 56

However, gene transfer (HNGT), which involves modifying the gene of the reproductive lineage for reproductive purposes, is still forbidden in the Great Britain under the," Human Fertilization and Embryology Act 1990 (HFE)."

The Great Britain allowed the first license to genetically modify embryos (for research purposes). There were not many laws related to gene editing, but the main reference point was the," Human Fertilization and Embryology Act of 1990 and 2008 to edit the germ cell genome".

Based on the ,"Human Tissue Act of 2004," for modifying somatic cells, the Secretary of State may, in light of improvements in science or medicine, alteration the definition of embryo oval- sperm-gamete to contain these new developments.

Article §3 (5) HFEA (the Human Fertilization and Embryology Act) 2008 added in §3ZA HFEA 1990 defines "permissible eggs, permissible sperm" and "permissible embryos."

This provision brings the law up to date with contemporary knowledge related to human gene editing.

Although the point that most of the §3ZA HFEA 1990 forbids humankind gene modifying resultant in an acceptable gametes or embryos, §3ZA (5) states, "Regulations may provide that the egg and embryo may be allowable to be genetically modified" although "The fetal egg has been subjected to, under specific conditions, a specific process aimed at preventing the transmission of a serious mitochondrial disease."

Additionally, "The Human Fertilization and Embryology (Mitochondrial Donation) Regulations of 2015," opened the door to germline editing under specific criteria and circumstances.

Consequently, the above laws allow germ line editing as there are specific regulations on this issue that have been agreed (to permit mitochondrial replacement techniques) which unlocks the door to editing in precise situations by modifying embryos.

The Scope of Canada Law:

According to, "Assisted Human Reproduction Act (S.C. 2004, c. 2), Article 5/f (prohibited procedures)," states, it is not permissible for anyone to change the genome of a human cell or embryo in the laboratory so that the change is transmittable to descendants. Paragraph 2 of Article 5, declares no person may offer to do or advertise to do anything prohibited by this section. Paragraph 3 stipulates, a person must not pay or offer to pay any person for doing anything prohibited under this section. However, this act lacks any sanctions.

The scope of German law: In accordance with Germany Embryonenschutzgesetz (Embryo Protection Act) in 1990, § (5 artificial alteration of human germ line cell), states,

"(1) anybody who artificially adjusts the genetic data of a humankind germ cell shall be penalized by confinement for a term of up to 5 years or by a fine.

(2) Anyone who usages a humankind germ cell containing artificially modified genetic information in the fertilization process shall also be punished."

The law includes elements of at least 28 offenses and it is most likely to affect the genetic dignity of a human being and human embryos for example: creating double maternity; support for surrogate motherhood; creating and using embryos for unrelated purposes, especially for scientific research; pregnancy with more than three fetuses; intentional creation and others.

The Conclusion

Results:

The current study revealed that the human genome is the most prominent international scientific project in biology in the twentieth century in terms of treating genetic diseases. Modifying the human genome may enhance people's ability to treat and recover from diseases, but the full effect cannot be achieved unless this practice is generalized to everyone instead of further deep inequality in the health field between and within countries. To avoid future risks of human gene editing and its impact on successive generations, the researcher reaches a number of suggesting as follows:

Recommendations:

1-A law that prohibits the use of the human genome should be enacted in any way with the intention of altering or modifying the embryos of people, whether this is to improve their lineage, purify the human race, or otherwise. In contravention of laws, regulations, and instructions.

2- It is prohibited for any health facility to provide services related to the human genome, which include genetic research - analysis of biological samples - storage, preservation, and transfer of genetic samples and data, except with a license from the competent health authority. These facilities may not advertise these services in various media outlets except with a license from the responsible authority and in accordance with the legislation regulating this matter.

3- Fine, severe imprisonment, and complementary penalties (confiscation - closing the place where the crime occurred) should be imposed on anyone who subjects any person to participate in or modify genetic tests without obtaining his/her consents or the consent of his/her legal representative if he/she is under age or incapacitated. Likewise, whoever takes, analyzes,

stores circulates, transports or destroys a genetic sample in violation of the law or attempts to do so should be punished with a fine and imprisonment.

4- Severe prison sentence and complementary penalties (confiscation - closing the place where the crime occurred) should be imposed on anyone who conducts any clinical study related to genes on humans with the aim of human cloning or modifying the human characteristics of people and embryos, or that involves the risk of generating dangerous genetically modified biological organisms on humans and the environment, or an attempt to do so.

5- Legal persons should be punished with a fine and severe imprisonment if their representatives, directors, or agents commit or attempt the crimes referred to above on their behalf or in their name. This does not prevent the imposition of complementary penalties (confiscation - closing the place where the crime occurred).

6- Administrative penalties on entities that violate the law should be imposed.

Footnotes

[1] Danil Sergeev, "The First Case of Human Genome Editing: Criminal Law Perspective," ***BRICS Law Journal*** 6, no. 4 (2019): 114–33 , p.115, https://doi.org/10.21684/2412-2343-2019-6-4-114-133.

[2] *Ibid*.

[3] Ahmed Saad Muhammad, "Constitutional Principles Relating to the Human Genome," ***Journal of Legal and Economic Studies*** 8, no. 0 (2022): 1–45, p3, https://doi.org/10.21608/jdl.2022.258901.

[4] Mutair, Mahdi, and Husam Abdul Ameer. 2023. "Standard Protection for the Human Genome". Journal of Legal Sciences 37 (August): 667-97. https://doi.org/10.35246/jols.v38i2.690.

[5] Mahdi Kazem Mutair, "**International Protection of the Human Genome"** (Baghdad University, 2023).p.7.

[6] Hassan Shamsi Pasha, "Genetics and Genetic Engineering," ***Islamic Culture Magazine*** 13, no. 1 (2017): 199–270, p.200, https://www.asjp.cerist.dz/en/article/156137.

[7] Mutair, "International Protection of the Human Genome." P.10.

[8] Pasha, *Ibid,* p.201.

[9] Pasha. *Ibid* ,p.32.

[10] Mutair , "Standard Protection for the Human Genome."*Ibid*, p.11.

[11] Pasha, *Ibid* , p.13.

[12] Pasha., *Ibid.* Article 13 of the Oviedo Convention (the first binding instrument in the field of biomedicine) indicated "، An intervention aimed at modifying the human genome may only be carried out for preventive reasons, for diagnostic or therapeutic purposes and only if the aim is not to introduce any modification into the genome of any descendants."

The legal protection of the human genome includes the protection of a group of rights, including :**the right to respect human dignity** (Article 1 of the Universal Declaration of Human Rights of 1948), **the right to bodily integrity** (Article 1 of the Universal Declaration of Human Rights, the European Convention on Human Rights and Fundamental Freedoms, and Article 17 of International Convention on Civil and Political Rights)

The human right to dispose of one's own body (Article D of the European Convention on Human Rights, Article 13 of the Council of Europe Human Rights Convention on Human Rights and Biomedicine). **The right to life** stipulated in most international instruments, including (the American

Convention, which indicated that the law must protect the right to life from the moment of conception).**The right to health, the right to enjoy the benefits of scientific progress, and the freedom of scientific research** stipulated in various international conventions

[13] Mutair, "International Protection of the Human Genome." *Ibid* ,p.12-13.

[14] Mutair. *Ibid*,p.13.

[15] Hossam Abdel Amir Khalaf, "International Protection of the Human Genome," ***Al-Haqiqah Journal for Humanities and Social Sciences*** 4, no. 20 (2021): 1–26, .2,pfile:///C:/Users/SFM/Downloads/ الحماية-الدولية-للجينوم-البشري ١)).pdf.

[16] Mutair, *Ibid,p.12*. "International Protection of the Human Genome."

[17] Khalaf, Hussam Abdel Amir, and And Muhammad Ismail Al-Arkawi, (2021). "Safeguarding the Intangible Heritage During Armed Conflict". Journal of Legal Sciences 36 (December): 337_362. https://doi.org/10.35246/jols.v36i0.420.

[18] Mutair, "International Protection of the Human Genome." *Ibid,p13-12*

[19] Dani Alves, Caso Koldo, and Cometa Halley, "Si Pensabas Que Eras Único, Lo Sentimos, Eres Un 99,9% Igual a Los Demás," (June 5, 2016) https://www.lavanguardia.com/vivo/salud/20160603/402248123540/no-eres-unico-adn.html.

[20] Pasha, "Genetics and Genetic Engineering." *Ibid,*p.62.

[21] Adnan Abbas Musa, "The Moral Responsibility of the International Community Regarding Human Cloning," ***Journal of Political Science*** 43 (2011): 75–104,p.78. https://doi.org/https://doi.org/10.30907/jj.v0i43.233.

[22] Pasha, *Ibid* ,p66.

[23] Mutair, "International Protection of the Human Genome." *Ibid,*p.13.

[24] Hani Khalil Rizk, ***A Brief History of the Universe: From the Big Bang to Human Cloning***, 1st ed. (Damascus: Dar Al Fikr, 2003).p.66.

[25] Rizk. *Ibid,*87.

[26] Pasha, "Genetics and Genetic Engineering." *Ibid,*p.66.

[27] Rizk, *Ibid , p.87.*

[28] Ralf Dahm, "Friedrich Miescher and the Discovery of DNA," ***Developmental Biology*** 278, no. 2 (2005): 274–88, p. 288, https://doi.org/10.1016/j.ydbio.2004.11.028.

[29] Dahm. *Ibid,* p.271. and see Majeed, Sahar Fouad, Artificial Intelligence Technology in the Field of Modern Forensic Evidence "Brain Fingerprinting as a Model," Vol.16,No.3,2024. P. 518. (513-530).

[30] Rizk, *Ibid,*p.87.

[31] D W Rudge, "The Man Who Invented the Chromosome," ***Heredity*** 97, no. 2 (2006):p.136, https://doi.org/10.1038/sj.hdy.6800856.

[32] Rudge. *Ibid.*

[33] Marie-Josée BERNARDI, "Diversité Génétique Humaine : Éléments d'une Politique," ***Thémis à l'adresse Suivante*** 35 (2001): 327–406,p.330. https://ssl.editionsthemis.com/uploaded/revue/article/rjtvol35num1_2/bernardi.pdf.

[34] Mutair, "International Protection of the Human Genome." *Ibid,*p.66.

[35] BERNARDI, "Diversité Génétique Humaine : Éléments d'une Politique." *Ibid,*p.335.

[36] Emmanuelle Laforêt Christian Hervé, Michèle S. Jean, Patrick A. Molinari, Marie-Angèle Grimaud and Avec, "**Généticisation et Responsabilités,"** in *Cet Ouvrage Est Issu Des Actes Du Septième Séminaire d'experts Franco-Québécois de l'Institut International de Recherche En Éthique Biomédicale (IIREB)* (France: à l'Université René-Descartes (Paris V), 2008), http://ethique.sorbonne-paris-cite.fr/sites/default/files/dalloz_2008_0.pdf.

[37] Mahmoud Abdel Rahim Mahran, ***Sharia and Legal Provisions for Intervention in the Factors of Heredity and Reproduction,*** 1st ed. (Egypt: Modern Renaissance House, 2001).p.136.

[38] Tariq Abdullah Muhammad Abu Hawa, "**Legal Repercussions of Artificial Reproduction, 'a Comparative Study,**'" (Mansoura University, 2009).p.401.

[39] Hawa. *Ibid,*p402.

[40] André Giudicelli, "**Génétique Humaine et Droit** : À La Redécouverte de l'homme," *Angewandte Chemie International Edition, 6(11), 951–952.* (: Université de Poitiers. UFR, 1993).p.113.

[41] Jenna Smith, ***The Era of Postgenomics***, *Вестник Росздравнадзора*, 1st ed., vol. 1469 (Egypt: National Center for Translation, 2010).p.286.

[42] Governance. National Academies of Sciences, Engineering, and Medicine; National Academy of Medicine; National Academy of Sciences; Committee on Human Gene Editing: Scientific, Medical, and Ethical Considerations. Human Genome Editing: Science, Ethics, ***Human Genome Editing,*** *Washington (DC):*

National Academies Press (US), 1st ed. (Washington (DC), 2017), 12,https://doi.org/10.5840/ncbq201717110.

[43] Sergeev, *Ibid*,p.114.

[44] Mutair, *Ibid*,p,68.

[45] Sergeev, *Ibid* .

[46] Motoko Araki and Tetsuya Ishii, "I**nternational Regulatory Landscape and Integration of Corrective Genome Editing into in Vitro Fertilization,**" *Reproductive Biology and Endocrinology* 12, no. 1 (2014):p. 1–12, https://doi.org/10.1186/1477-7827-12-108.

[47] Sergeev, *Ibid ,p.126.*

[48] David Cyranoski, "China Set to Introduce Gene-Editing Regulation Following CRISPR-Baby Furore," Nature- National lLbrary of Medicine, 2019, https://doi.org/10.1038/d41586-019-01580-1.

[49] Lingqiao Song and Yann Joly, "After He Jianku : China ' s Biotechnology Regulation Reforms," ***Medical Law International*** 21(2), no. January (2021): 174–91, https://doi.org/10.1177/0968533221993504.

[50] Cyranoski, *Ibid* .

[51] Britta C van Beers, "Rewriting the Human Genome , Rewriting Human Rights Law ? Human Rights , Human Dignity , and Human Germline Modification in the CRISPR Era," ***Journal of Law and the Biosciences*** 7(1), no. lsaa006 (2020),p. 9, https://doi.org/10.1093/jlb/lsaa006.

[52] Muhammad, *Ibid ,p.34.*

[53] *Ibid ,p.35.*

[54] *Ibid* .

[55] *Ibid.*

[56] *Ibid.*

References

Books

I. Mahran, Mahmoud Abdel Rahim. *Sharia and Legal Provisions for Intervention in the Factors of Heredity and Reproduction*. 1st ed. Egypt: Modern Renaissance House, 2001.

II. Rizk, Hani Khalil. *A Brief History of the Universe: From the Big Bang to Human Cloning*. 1st ed. Damascus: Dar Al Fikr, 2003.

III. Smith, Jenna. *The Era of Postgenomics*. *Вестник Росздравнадзора*. 1st ed. Vol. 1469. Egypt: National Center for Translation, 2010.

Dissertation and Theses.

i. Giudicelli, André. "Génétique Humaine et Droit : À La Redécouverte de l'homme." *Angewandte Chemie International Edition, 6(11), 951–952.* : Université de Poitiers. UFR, 1993.

ii. Hawa, Tariq Abdullah Muhammad Abu. "Legal Repercussions of Artificial Reproduction, 'a Comparative Study,.'" Mansoura University, 2009.

iii. Mutair, Mahdi Kazem. "International Protection of the Human Genome." Baghdad Universit, 2023.

iv. National Academies of Sciences, Engineering, and Medicine; National Academy of Medicine; National Academy of Sciences; Committee on Human Gene Editing: Scientific, Medical, and Ethical Considerations. Human Genome Editing: Science, Ethics, and Governance. *Human Genome Editing*. *Washington (DC): National Academies Press (US)*. 1st ed. Washington (DC), 2017. https://doi.org/10.5840/ncbq201717110.

Research Paper

i. Araki, Motoko, and Tetsuya Ishii. "International Regulatory Landscape and Integration of Corrective Genome Editing into in Vitro Fertilization." *Reproductive Biology and Endocrinology* 12, no. 1 (2014): 1–12. https://doi.org/10.1186/1477-7827-12-108.

ii. Beers, Britta C van. "Rewriting the Human Genome , Rewriting Human Rights Law ? Human Rights , Human Dignity , and Human Germline Modification in the CRISPR Era." *Journal of Law and the Biosciences* 7(1), no. lsaa006 (2020). https://doi.org/10.1093/jlb/lsaa006.

iii. BERNARDI, Marie-Josée. "Diversité Génétique Humaine : Éléments d'une Politique." *Thémis à l'adresse Suivante* 35 (2001): 327–406. https://ssl.editionsthemis.com/uploaded/revue/article/rjtvol35num1_2/bernardi.pdf.

iv. Christian Hervé, Michèle S. Jean, Patrick A. Molinari, Marie-Angèle Grimaud, Emmanuelle Laforêt, and Avec. "Généticisation et Responsabilités." In *Cet Ouvrage Est Issu Des Actes Du Septième Séminaire d'experts Franco-Québécois de l'Institut International de*

Recherche En Éthique Biomédicale (IIREB). France: à l'Université René-Descartes (Paris V), 2008. http://ethique.sorbonne-paris-cite.fr/sites/default/files/dalloz_2008_0.pdf.

v. Cyranoski, David. "China Set to Introduce Gene-Editing Regulation Following CRISPR-Baby Furore." Nature- National lLbrary of Medicine, 2019. https://doi.org/10.1038/d41586-019-01580-1

vi. Dahm, Ralf. "Friedrich Miescher and the Discovery of DNA." *Developmental Biology* 278, no. 2 (2005): 274–88. https://doi.org/10.1016/j.ydbio.2004.11.028.

vii. Mutair, Mahdi, and Husam Abdul Ameer. 2023. "Standard Protection for the Human Genome". Journal of Legal Sciences 37 (August): 667-97. https://doi.org/10.35246/jols.v38i2.690.

viii. Khalaf, Hussam Abdel Amir, and And Muhammad Ismail Al-Arkawi, (2021). "Safeguarding the Intangible Heritage During Armed Conflict". Journal of Legal Sciences 36 (December): 337_362. https://doi.org/10.35246/jols.v36i0.420.

ix. Khalaf, Hossam Abdel Amir. "International Protection of the Human Genome." *Al-Haqiqah Journal for Humanities and Social Sciences* 4, no. 20 (2021): 1–26. file:///C:/Users/SFM/Downloads/الحماية-الدولية-للجينوم-البشري (١).pdf.

x. Majeed, Sahar Fouad, Artificial Intelligence Technology in the Field of Modern Forensic Evidence "Brain Fingerprinting as a Model," Vol.16, No.3, 2024. (513-530). https://doi.org/10.62271/pjc.16.3.513.530

xi. Muhammad, Ahmed Saad. "Constitutional Principles Relating to the Human Genome." *Journal of Legal and Economic Studies* 8, no. 0 (2022): 1–45. https://doi.org/10.21608/jdl.2022.258901 .

xii. Musa, Adnan Abbas. "The Moral Responsibility of the International Community Regarding Human Cloning." *Journal of Political Science* 43 (2011): 75–104. https://doi.org/https://doi.org/10.30907/jj.v0i43.233.

xiii. Pasha, Hassan Shamsi. "Genetics and Genetic Engineering." *Islamic Culture Magazine* 13, no. 1 (2017): 199–270. https://www.asjp.cerist.dz/en/article/156137 .

xiv. Rudge, D W. "The Man Who Invented the Chromosome." *Heredity* 97, no. 2 (2006): 136–136. https://doi.org/10.1038/sj.hdy.6800856.

xv. Sergeev, Danil. "The First Case of Human Genome Editing: Criminal Law Perspective." *BRICS Law Journal* 6, no. 4 (2019): 114–33. https://doi.org/10.21684/2412-2343-2019-6-4-114-133.

xvi. Song, Lingqiao, and Yann Joly. "After He Jianku : China ' s Biotechnology Regulation Reforms." *Medical Law International* 21(2), no. January (2021): 174–91. https://doi.org/10.1177/0968533221993504.