

ETHICAL AND SOCIO-CULTURAL DIMENSIONS OF HUMAN GENOME EDITING – WAR AGAINST NATURAL ORDER

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Abstract

Human genome editing is part of scientific and human efforts to tackle health challenges and to improve health and general well-being. The World Health Organisation describes human genome editing as a method for making specific changes to the DNA of a cell or organism. The modification of human DNA carries with it, contemporary realities and challenges of ethical concerns and regulation. Subjecting human beings to such delicate procedure calls for scrutiny and meticulous monitoring because of the possibility of mutations and other medical issues that could endanger public health and infringe human rights. The concept of human rights is inherent in human beings simply because of their humanity and these rights are inalienable. They are based on respect for the individual, who has the right to be treated with dignity and Governments are obliged to protect and uphold the human rights of their citizens. This paper therefore attempts to identify and consider ethical and socio-cultural dimension of human genome editing paying due attention to moral conflicts that may occur. In doing this, principle of Utilitarianism and Universality of Rights will guide the study.

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Utilitarianism, as propounded by Bentham, prioritises the welfare of the greatest happiness of the greatest number. Whilst recognising the possibility of human rights infringement and the fact that encouraging genome editing may seem like “playing God”, with the tendency of getting out of hand, where the overall good outweighs the projected “evil”, it should be permitted. The paper adopts the doctrinal and analytical legal research methodologies.

Keywords: Ethical Concerns, Common Good, Human Rights and social justice

1.0 Introduction

Developments and improvements of the science and technology is a reality of the 21st century. Advancement in medical science is a welcome technology which is aimed at improving the general well-being human race. Human genome editing is one of the innovations in the medical field and it refers to the use of technology to make precise, intentional changes to the DNA of a human being. This technology has the potential to cure or prevent genetic diseases, but it also raises many ethical concerns and potential risks. As with other technological or scientific advancement, human genome editing has come with its merits and demerits and since it is an invasive procedure. It is indeed an invasive procedure because it is used to diagnose and possibly treat certain genetic conditions and in reality, it carries with it such risks as bleeding, infection, and damage to surrounding tissues or organs.¹

Genome editing has been employed in making additions, deletions and substitutions to genome. The growth of new methods has made editing of the genome much more defined, properly delineated, efficient,

¹ National Institutes of Health
(https://www.nlm.nih.gov/nichsr/instru_terms/invasive_procedure.html)

malleable and cheaper in comparison to prior plans.² Genome editing has been classified into two main types which are somatic and germline. The classification of genome editing into somatic and germline types is a widely recognised categorisation within the scientific community.³ Somatic genome editing entails changing the DNA of specific cells in a person's body to treat a particular disease or condition. These changes are not however not transferred to future generations. On the other hand, Germline genome editing involves making changes to the DNA of reproductive cells or embryos. These changes are transferable and can be passed down to future generations and could potentially alter the genetic makeup of the human species.⁴ As somatic genome editing is already being used to treat certain genetic diseases, germline editing still remains a controversial topic with many ethical and safety concerns.

With regards to basic science research, genome editing technologies have been used extensively. Whilst in clinical applications of somatic cells, the use of human genome editing is still at its early stages. Though frowned against in most jurisdictions, as it produces heritable changes, it may be used in clinical applications of reproductive cells, in the future.⁵ Since Genome editing is at its formative stage it is thus expedient to inculcate some form of regulatory procedure which will act as check and balances for the practitioner.

Over the years, the impact of human genome editing in precision medicine, is enormous. There are different techniques for human

² EPRS | European Parliamentary Research Service, Scientific Foresight Unit (STOA) 2020 Genome editing in humans; A survey of law, regulation and governance principles Panel for the Future of Science and Technology,

³ Doudna, J. A., & Charpentier, E. (2014). Genome editing. The new frontier of genome engineering with CRISPR-Cas9. *Science*, 346(6213), 1258096. <https://doi.org/10.1126/science.1258096>

⁴ Ibid.

⁵ National Academies of Sciences, Engineering, and Medicine. 2017. Human Genome Editing: Science, Ethics, and Governance. Washington, DC: The National Academies Press. doi: <https://doi.org/10.17226/24623>.

genome editing, the latest being CRISPR-Cas9. This technique has become very popular, given its ease of use and efficiency. As noted earlier, the use of human genome editing is two folds. It is used in somatic cells application, in relation to treating and preventing diseases, and in gametes/embryos research or germline modification in human reproduction.

The use of human genome editing has ethical, social and political impact, leading to the emergence of varying regulatory interventions from professional and governmental organisations.⁶ The advent of the CRISPR genome editing technology in 2012, escalated the debate on the social and ethical permissibility or otherwise and consequences of heritable human genome editing.⁷ Heritable genome editing occurs when embryos are genetically modified and implanted in the uterus, thereby initiating pregnancy, which could result in the delivery of a child with modified genes. These modified genes can be passed on to descendants of that child.

Opportunities presented by human genome editing are enormous, as evidenced in recent advancements in personalised medicine. This has intensified the debate amongst scientists, policymakers and lawmakers, on its use. Its use has raised not only scientific concerns, but ethical as well as governance challenges. Questions asked include, “should it be allowed, “for what purpose(s)?”, and “what boundaries, if any, should be set?”⁸

⁶ Kane, E.M., 2017. Human Genome Editing: An Evolving Regulatory Climate. Forthcoming in *Jurimetrics* Vol. 57 Issue No. 3 (Spring 2017).

⁷ Germline gene editing or gene editing in gametes or reproductive cells make a permanent change to the reproductive cells that could be passed on to future generations.

⁸ Brigden, T. 2021. What Does ‘Good Governance’ Look Like For Genome Editing?. Retrieved 12 April, 2023 from <https://www.phgfoundation.org/blog/what-does-good-governance-look-like-for-genome-editing>

In November 2018, a Chinese Scientist named He Jiankui claimed that, in a secret experiment, he successfully edited the genome of twins.⁹ While Jiankui has since been sentenced to three years in prison for violating regulations, this debate has continued to grow in intensity. The announcement¹⁰ by He Jiankui, in 2018, about his genetically modified twins brought a rude awakening to the world about the extent and rapid development of the CRISPR-Cas 9, genome editing technology. The discovery had been envisaged as a subsequent possibility, resulting from germline human genome editing.¹¹ It has been the reason why nations around the world have either made it illegal or licenced the procedure, in limited circumstances.¹² In making these babies, the Chinese scientist claimed to have used the CRISPR-Cas9 technology to modify the DNA of human embryos and implanted it the womb of the children's mother. The essence of this procedure was to create babies who will be immune or resistant to HIV. In carrying out this procedure, He Jiankui breached scientific conventions and created genetic "changes that had never been seen in humans before".¹³ He was described as ignoring the bioethical principle of *non maleficence*, and will be remembered for carrying out "the most shocking misapplication of any scientific tool in our history."¹⁴

This discovery presented an awakening to the possibilities of human germline gene editing and its implications for human reproduction. It

⁹ Saleem,H , Khaskheli M, Fareed,S. 2019 **Legal framework for gene editing in human genome "World's First Mutant twins by China.** IOSR Journal Of Humanities And Social Science (IOSR-JHSS) Volume 24, Issue 2, Ser. 1 25-32. Retrieved www.iosrjournals.org

¹⁰ On YouTube - ¹⁰ The He Lab, *About Lulu and Nana: Twin Girls Born Healthy After Gene Surgery As Single-Cell Embryos*, www.youtube.com/watch?v=th0vnOmFltc> accessed 12th January, 2023.

¹¹ Sharon Begley & Andrew Joseph, *The CRISPR shocker: How Genome-Editing Scientist He Jiankui Rose From Obscurity to Stun the World*, STAT, Dec. 18, 2018.

¹² United Kingdom position.

¹³ Greely, *CRISPR'd babies*, *supra* note 5, at 117.

¹⁴ Jennifer Doudna, *He Jiankui*, Time Magazine, Apr. 29, 2019.

revealed the possibility of an individual being capable of taking genetic fate into their hands. Prior to this, the extent of reproductive technologies had been limited to non-invasive prenatal testing and preimplantation genetic diagnosis, with the child's entire genetic profile being the result of biological combination of parental genes. CRISPR-Cas9 has however provided the possibility of parents genetically modifying their offspring.¹⁵

In another incidence, Denis Rebrikov, a Russian scientist, was reported to have used edited human eggs, which had been used in preventing deafness, to bring about the occurrence of pregnancy.¹⁶ Whilst human genome editing has obvious disadvantages and negative aspects, on the flip side, it holds significant promises. The World Health Organisation (WHO) states that an error in a single gene, which occurs in about one percent (1%) of births, has been known to cause over ten thousand (ten thousand) monogenic diseases.¹⁷ These diseases can be deadly, reducing the quality of life. However, the application of human genome editing can alleviate, and possibly eradicate the consequences of these diseases. It has been proposed as a tool for addressing more complex disorders, such as cancer, cardiovascular diseases and even, diabetes.¹⁸ The debate about acceptability of human genome editing is ongoing. It is accepted that it has definite advantages. It offers possibly lasting solutions in treating and preventing diseases such as, sickle-cell anemia,

¹⁵Sternberg S H. 2019. The Biological Breakthrough of CRISPR- Based Gene Editing in *Towards a New Enlightenment? A Transcendent Decade*. p. 2. <<https://www.bbvaopenmind.com/en/books/towards-a-new-enlightenment-a-transcendent-decade/>> on 14th April, 2023.

¹⁶Yotova, R 2020. *Regulating Genome Editing Under International Human Rights Law*. Cambridge University Press for the British Institute of International and Comparative Law.

¹⁷ WHO. Genes and human diseases [EB/OL]. [2019-03-21]. <<http://www.who.int/genomics/public/geneticdiseases/en/>> .

¹⁸Yotova, R 2020. *Regulating Genome Editing Under International Human Rights Law*. Cambridge University Press for the British Institute of International and Comparative Law.

cancer, hemophilia and HIV/AIDS.¹⁹ However, the dangers that it can result in, cannot be overlooked, as it is susceptible to unethical, unjustifiable and unacceptable practices. The consensus among experts, with the National Academy of Science, therefore is to accept human genome editing, but with strict monitoring and adherence to ethical principles.²⁰

Ethical and regulatory challenges posed by germline editing are causes for concern, given that their consequences can be irreversible, unintended negative changes, which can be hereditary. These negative effects can affect generations, and possibly impacting humanity.

2.0 Conceptual Clarifications

- i. **DNA:** These are the molecule inside cells which contain the genetic information responsible for the development and function of an organism. The DNA molecules permit this information to be passed from one generation another. It is made up of a double-stranded helix held together by weak hydrogen bonds between purine-pyrimidine nucleotide base pairs.²¹
- ii. **Gene therapy:** involves either replacing a faulty gene with a healthy gene or adding a new gene in an attempt to prevent disease. Although promising, at the moment, gene therapy is still experimental and the only way to receive gene therapy would be to participate in an experimental clinical trial.²²

¹⁹ *ibid*

²⁰ National Academy Of Sciences, Human Genome Editing: Science, Ethics, And Governance 7-8 (2017).

¹⁵ See David Shaw

²¹ "DNA". <<https://www.cancer.gov/publications/dictionaries/genetics-dictionary/def/dna>> Accessed on 15/4/2023.

²² "What is Gene Therapy?" <<https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy#:~:text=Gene%20therapy%20is%20a%20technique,that%20is%20not%20functioning%20properly>> Accessed on 15/4/2023.

- iii. **Gene:** a gene is a section of DNA that holds the code (or 'codes for') a specific protein. There are about 24,000 different genes in humans. Errors in the order of the string of letters of a gene are called mutations, and these can result in a faulty protein or even prevent a protein being made.²³ People with cystic fibrosis are born with an error (or 'mutation') in the cystic fibrosis gene, resulting in a faulty protein.
- iv. **Genome editing techniques:** can be used to make changes to a cell's DNA. They enable the targeted modification of DNA sequences within living cells. Their potential uses are found in biomedical research, human therapy, agriculture and to help control vector-borne diseases.²⁴
- v. **Genome:** all of the DNA in a cell²⁵
- vi. **Human Germline Genome Editing (HGGE):** The methods used to make changes to human eggs, sperms or embryo (germline cells)²⁶
- vii. **Proteins:** these consists of large, complex molecules that play many critical roles in the body. They do most of the work in cells and are required for the structure, function, and regulation of the body's tissues and organs.²⁷

²³ "What Is A Gene?" <<https://medlineplus.gov/genetics/understanding/basics/gene/>> Accessed on 15/4/2023

²⁴ UK Parliaments. Parliamentary Office for Science and Technology (POST) Note 541 of 2016. p.1 <<https://post.parliament.uk/type/postnote/>> Accessed on 15/4/2023. POST Note 611. 2020. Human Germline Genome Editing. A publication of the UK Parliamentary Office for Science and Technology. <<https://post.parliament.uk/type/postnote/>> Accessed on 15/4/2023

²⁵ "Genome" <<https://www.cancer.gov/publications/dictionaries/cancer-terms/def/genome>> Accessed on 15/4/2023.

²⁶ Ormond, K. E. et al. (2017). Human Germline Genome Editing. The American Journal of Human Genetics, Vol 101, 167–176. Referred to in POST Note 611.

²⁷ What are proteins and what do they do? <<<https://medlineplus.gov/genetics/understanding/howgeneswork/protein/#:~:text=P,roteins%20are%20large%2C%20complex%20molecules,the%20body's%20tissues%20and%20organs.>>> Accessed on 15/4/2023

3.0 The Advent of Human Genome Editing

Historical the first genome editing technologies were developed in the late 1900s. Editing of genome allows scientists to make adjustments to DNA (Deoxyribonucleic acid).²⁸ This naturally would have consequences which may eventually completely alter the biological traits of an individual. One of the positive side of genome editing is that it helps in the investigation of different diseases that affect human beings. In addition, genome editing is also used for the treatment of diseases.²⁹ For instance, genome editing has aided researchers to identify the genetic causes of various diseases, such as cystic fibrosis and sickle cell anemia. It has also allowed them to develop new therapies for these diseases by modifying the patient's genetic tissue.³⁰ In recent times, an innovative genome editing tool referred to as CRISPR, was conceived and invented in 2009.³¹ This innovation has made easier to edit DNA. CRISPR is less complicated, faster, relatively cheaper and more precise than older genome editing methods.³² As a matter of fact, many scientist who perform genome editing now employ the use of CRISPR. Many scientists and ethicists believe that germline editing should not be pursued until the risks and ethical considerations have been thoroughly addressed.

Overall, human genome editing is a rapidly developing field with enormous potential for improving human health, but it must be approached with great caution and careful consideration of the ethical

²⁸ DNA stands for Deoxyribonucleic acid, which is a molecule that contains genetic information and is responsible for the inheritance of traits in all living organisms.

²⁹ Doudna, J. A., & Charpentier, E. (2014). The new frontier of genome engineering with CRISPR-Cas9. *Science*, 346(6213), 1258096. doi: 10.1126/science.1258096.

³⁰ Doudna, J. A., & Charpentier, E. (2014). *Ibid*

³¹ Jinek, M., Chylinski, K., Fonfara, I., Hauer, M., Doudna, J. A., & Charpentier, E. (2012). A programmable dual-RNA-guided DNA endonuclease in adaptive bacterial immunity. *Science*, 337(6096), 816-821.

³² What is genome editing? <https://www.genome.gov/about-genomics/policy-issues/what-is-Genome-editing>

implications. Editing DNA can lead to transformation or changes in physical traits like the colour of the eyes and potential disease risk. Human genome editing is a swiftly evolving field with great prospect and enormous potential for improving human health and treatment of genetic disorders.³³ As laudable as the benefits of this procedure are, there are also significant issues of concern associated with this technology which must be addressed. The major issues against human genome editing can be categorised into legal, social and ethics.³⁴ Apart from the ethical contemplations surrounding human genome editing, there are other there are other complicated moral issues which should be considered. For instance creation by alteration of natural biological order like *designer babies* and some unforeseen circumstances which may occur with unimaginable and unplanned consequences is an ethical concern regarding genome editing.³⁵ This could lead to a "genetic arms race" and aggravate existing inequalities, further dividing society into genetic haves and have-nots.³⁶

The risk factors of Genome Editing include the following. However, the risk factors are not limited to these as the medical procedure is gradually gaining momentum being at its formative stage.

1. Ethical Issues: There are a number of ethical issues involved in the practice of genome editing which would be elaborated upon in the course of this study.
2. Off-target effects: it is common knowledge that no human activity or intervention is perfect and always true to precision because of the fickleness of human nature thus, there would be some elements of imperfections. In line with this, Genome editing is not yet perfect

³³ Mali P, Yang L, Esvelt KM, Aach J, Guell M, DiCarlo JE, Norville JE, Church GM. (2013) RNA-guided human genome engineering via Cas9. *Science* 339(6121):823-6.

³⁴ National Academies of Sciences, Engineering, and Medicine. (2017). *Human Genome Editing: Science, Ethics, and Governance*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/24623>

³⁵ *ibid*

³⁶ *Ibid.*

because it is still being developed and improved upon. Thus, this can result in what is referred to as off-target effects in circumstances where unintended changes occur to the genome. Off-target effects can result in dangerous genetic mutations, with loss of gene function as a consequence, such as cancer cells in animals and undesirable phenotype (disease sensitivity) in plants.³⁷ The off-target effects can lead to unpredictable and potentially harmful outcomes.³⁸ Off-target effect that can also occur when a drug binds to unintended targets (proteins or other molecules in the body). This can lead to unexpected, harmful side effects.³⁹ Consequences of off-target effects include, unintended point mutations, deletions, insertions inversions, and translocations. Given that designer nuclease systems such as CRISPR-cas9 are becoming increasingly popular research tools as a result of their simplicity, scalability and affordability and off-target consequences are likely to occur, there is the need to ensure compliance with ethical principles.⁴⁰

3. Limited Knowledge: In spite of the fact that the Human Genome Project was completed in 2003 and provided a blueprint for the human genetic code, it is important to note that the genome is extremely complex and full comprehension of the workings is yet to be fully understood as it is still developing.⁴¹ There is incomplete understanding of the genome because while much is known about the human genome, there is still much that is not understood. Researchers may inadvertently alter genes that they do not fully understand, leading to unexpected

³⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7407193/>

³⁸ Doudna, J. A., & Charpentier, E. (2014). Genome editing. The new frontier of genome engineering with CRISPR-Cas9. *Science*, 346(6213), 1258096. doi: 10.1126/science.1258096.

³⁹ National Cancer Institute Dictionary of Cancer Terms <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/off-target-effect>

⁴⁰ Gopalappa, R., & O'Connell, M. R. (2018). Off-target effects in CRISPR/Cas9-mediated genome engineering. *Molecular Therapy - Nucleic Acids*, 13, 1-12. doi: 10.1016/j.omtn.2018.05.008

⁴¹ Richard Julia E. & Hawley Scott R. 2011, *The Human Genome: A User's Guide*. Academic Press 3rd edn. <https://www.sciencedirect.com/book/9780123334459/the-human-genome#book-info>

outcomes. One of the reasons for this is that the genome is not just a static set of instructions. Instead, it interacts with the environment, and can be affected by a variety of factors such as diet, exercise, and exposure to toxins. This means that while we may have a basic understanding of what certain genes do, there are still many unknowns about how they interact with each other and with the environment.⁴²

Moreover, the bulk of the genome is made up of non-coding DNA, which does not directly code for proteins but may still have important regulatory functions. Facts about the role of non-coding DNA is still emerging and how it affects gene expression.⁴³ It is important to note that non-coding DNA is also known as "junk DNA," makes up the larger part of the human genome. While non-coding DNA does not directly code for proteins, it can still have important regulatory functions. For example, some non-coding DNA sequences contain regulatory elements that can control the expression of nearby genes. Other non-coding DNA sequences may play a role in the three-dimensional organization of the genome or in maintaining chromosome stability.⁴⁴ There is still a lot to be known about genetic variation between individuals and populations, and how this variation relates to disease risk and other traits though some significant progress in understanding the genome have been made.

4. Long-term effects: The long-term effects of genome editing are not yet known, and it is possible that unintended consequences may emerge years or even decades after the procedure. Apparently, the long-term effects of genome editing are still undergoing research and it is

⁴² Scharping Nathaniel 2021, "Finishing the Human Genome' This article appeared in the January/February 2022 issue of Discover magazine as "Finishing the Human Blueprint."

<https://www.discovermagazine.com/health/finishing-the-human-genome>

⁴³ The ENCODE Project Consortium. (2012). An integrated encyclopedia of DNA elements in the human genome. *Nature*, 489(7414), 57–74. <https://doi.org/10.1038/nature11247>

⁴⁴ Ibid.

probable that unplanned consequences may emerge years or even decades after the procedure.

Genome editing techniques such as CRISPR-Cas9 allow scientists to make precise changes to the DNA of living organisms, including humans, which can have a wide range of potential applications, from curing genetic diseases to improving crop yields. However, as with any new technology, there are potential risks and uncertainties associated with genome editing. While some studies have shown that genome editing can be done safely and effectively in certain contexts, other research has raised concerns about the potential for unintended off-target effects, which could lead to unexpected genetic changes that may have negative health outcomes. The unpredictability of the effects on future generations, as changes made to the DNA of an individual can be passed down to their offspring raises ethical concerns about the potential impact of genome editing on future generations and the need for responsible use of these technologies. Other risk factors include concerns of the availability and affordability of the technology which may further strain the financial imbalances in the society. Issues relating to monitoring and compliance with regulation are risk factors and also the challenge of abuse and the potential improper use.⁴⁵ The myth of the escape of a virus from a laboratory in Wuhan, China is still very fresh in the memory of people in the society thus, gene editing may be subjected to misuse for non-medical or nefarious purposes like the creation of genetically modified organisms or even weapons.⁴⁶

4.0 Ethical Issues in Human Genome Editing

Improper use of technology, has been cause of concern in the fields of Biology, Medicine and Law. Genome editing has an unprecedented potential to alter the future of humanity. As a matter of fact, its potential

⁴⁵ Oye, K. A., et al. (2017). Regulating Gene Editing: The Road Ahead. *Science*, 357(6351), 876-878.

⁴⁶ National Academies of Sciences, Engineering, and Medicine. (2018). *Biodefense in the Age of Synthetic Biology*. Washington, DC: The National Academies Press.

usage is not limited to the area of health, such as repairing, modulating, replacing and addition to existing gene.⁴⁷ As noted earlier, it can be used on somatic cells as well as reproductive cells, thereby altering, permanently, the genetic makeup of future generations. This has generated debates centred on its social, ethical and policy implications.⁴⁸ Application of gene editing tools such as CRISPR-Cas 9, in seeking solutions for treating or preventing diseases, improving understanding in science, raise ethical issues that require oversight. The recent COVID-19 pandemic, illustrated the necessity in developing new interventions and methods for dealing with life threatening diseases, and the relevance of human genome editing in such quests. Be that as it may, the need for care, quality assurance, cannot be overemphasized, in order to maximise benefit and minimize harm.⁴⁹

Human rights, in relation to human genome editing, are rights to autonomy, human dignity, equality and the right against discrimination. Other rights flow from the right to human dignity. The right to human dignity is however, difficult to conceptualise.⁵⁰ In addition to the right to human dignity, are the rights to health, the benefits from scientific researches.⁵¹ Also relevant are “rights” of future generations, which seeks to preserve intergenerational equity. There are concerns on the effect of germline editing in relation to interests of embryos and the

⁴⁷Slokenberga, S, Minssen,T, Nordberg A 2022. Governing, Protecting, and Regulating the Future of Genome Editing: The Significance of ELSPI Perspectives. *European Journal of Health Law* 29, 327–340

⁴⁸ Qaiser, F. 2020. Study: There is no country where heritable human genome editing is permitted. Retrieved April 12, 2023 from <https://www.forbes.com/sites/farahqaiser/2020/10/31/study-there-is-no-country-where-heritable-human-geno>

⁴⁹ WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing. Human Genome Editing: position paper. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

⁵⁰ Art 1, Universal Declaration of Human Rights; Preamble, para 2 of the UN Charter

⁵¹ See art 2 ICESCR; and Barcelona Traction Light and Power Company Limited, Second Phase, Judgment, ICJ Rep 1970, at paras 33–34.

rights of future generations, vis-à-vis the necessity for preserving the diversity of humanity, and the potential conflict of interests of parents and the embryos.

In discussing the ethical issues in human genome editing, this paper will examine ethical debates in relation to the individuals involved, the society in which they live and of humans, in general. Ethical concerns about reproduction and those directly involved, namely, parents and their future offspring, centres around Respect for reproductive goals, The desire for genetic relatedness, Respect for procreative interests, and the interests of the future person and Society. Heritable genome editing provides the means for an individual to have genetically related offspring, with the opportunity of determining the choice of heritable characteristics. At the of the individual, the effect of this may not be apparent. However, when it occurs in a large population, those pre-determine health related characteristics will affect the overall health of the whole. The ability to continuously alter the characteristics of future generations has heightened concerns about safety, especially, in relation to adverse effects, which may not be exhibited immediately, but incubated to a later date, by which time the alteration may have spanned more than one generation.

5.0 Legal and Regulatory Framework for Genome Editing

The possibility of detrimental societal and intergenerational consequences of human genome editing, has, over the years, generated debates about its social, ethical and policy implications.⁵² These debates are centred around whether to prohibit or strictly regulate its application, under states and/or international human rights laws, the relevant human rights norms and standards, the adequacy or otherwise of the existing international regulatory framework, and the possible need for developing new and specific standards. Also considered are the issues

⁵² Human genome editing has been raising controversy in the international medical space as there is no regulating body or laws to monitor what scientists do.

of the kind of safety guarantees that can be put in place and the required steps to effectively arrive at a balancing the risk/benefit ratio, and resolving the dilemma between upholding the autonomy and welfare of the individual and the interest of society and humankind.⁵³

As noted earlier, the controversy on accepting and on what conditions to accept human genome editing persists. A school of thought posits that, given its potential global impact, decisions on its acceptability should be a global consensus, using a treaty, moratorium or boycott, as opposed to individual states taking separate stands.⁵⁴ Their argument is based on the need to avoid its premature application to humans, given its potential risk factor.

International law plays an important role in regulating genome editing.⁵⁵ The international framework for human genome editing includes, the UNESCO Declaration on the Human Genome and Human Rights, 1997 and the UNESCO Declaration on Bioethics and Human Rights, 2005.⁵⁶ In addition is, the Committee on Economic, Social and Cultural Rights (ICESCR). By virtue of the ICESCR, states parties are obliged to regulate biomedical, life sciences and associated technologies studies, so as to prevent negative consequences of science and scientific researches.

⁵³Yotova, R 2020. *Regulating Genome Editing Under International Human Rights Law*. Cambridge University Press for the British Institute of International and Comparative Law.

⁵⁴ Shoji,B., Kamwendo,T., Kinderlerer,J., Donrich, W., Thaldar,D.W., Townsend,B., Botes,M. 2021. Future of global regulation of human genome editing: a South African perspective on the WHO Draft Governance Framework on Human Genome Editing. *J Med Ethics*: Retrieved from <http://jme.bmj.com>

⁵⁵International Organisations and non-governmental scientific organisations seem to agree that there is a need to establish an effective regulatory framework designed specifically to govern genome editing.

⁵⁶While not legally binding, the UNESCO Declaration sets out internationally agreed standards and good practices concerning genetic interventions, which were supported by a broad international consensus at the time of its adoption and are still pertinent today.

In 2019, the Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing (the Advisory Committee), was established by the WHO,⁵⁷ to *advise and make recommendations on appropriate institutional, national, regional and global governance mechanisms for human genome editing*.⁵⁸ The Advisory Committee's Measures and Guidelines, specifically prohibit the use of manipulated embryos, zygotes and genomes for reproduction. Bearing in mind that several nations have their national legislations and positions on human genome editing, this paper will discuss legal and regulatory framework for human genome editing, in Nigeria, the United Kingdom, and the United States. In addition, it will discuss the various relevant international initiatives.

6.0 Regulating Human Genome Editing in Nigeria

Regulating human genome editing in Nigeria is done using international, regional and national legislative instruments. Nigeria is a signatory to the Universal Declaration of Human Rights (UDHR) and the Universal Declaration on the Human Genome and Human Rights (UDHGHR), as well as the International Covenant on Economic, Social, and Cultural Rights, the International Covenant on Civil and Political Rights and the Convention on the Rights of the Child.

The UDHGHR is a non-binding declaration that sets out principles and guidelines for the protection of the human genome, including issues related to genetic research, genetic testing, and genetic privacy. While the declaration is not legally binding, it is widely considered to be an

⁵⁷<<https://www.who.int/teams/health-ethics-governance/emerging-technologies/expert-advisory-committee-on-developing-global-standards-for-governance-and-oversight-of-human-genome-editing>> on 12/4/2023

⁵⁸ WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing REPORT OF THE SECOND MEETING Geneva, Switzerland, 26–28 August 2019. p.1
<<https://www.who.int/publications/i/item/WHO-SCI-RFH-2019-02>> Accessed on 12/4/2023

authoritative document that sets out ethical standards for the use of genetic information.

Nigeria has also taken steps to incorporate some of the principles of the UDHGHR into its domestic law. For example, the National Health Act of 2014 provides for the protection of genetic information and prohibits genetic testing without informed consent.

In summary, while the UDHGHR is not a legally binding document, Nigeria has taken steps to incorporate some of its principles into domestic law and is bound by other international human rights treaties that protect the rights of individuals with respect to their genetic information. The National Biosafety Management Agency (NBMA) was established by the provisions of the National Biosafety Management Agency Act, 2015. In line with the provisions of the Act, the NBMA is empowered to identify and develop functional strategies to facilitate the implementation of the provisions of the Act. As a result of this, the NBMA has put together regulatory framework, as well as institutional and administrative mechanism for safety measures in the application of modern bio-technology on human health, animals, plants and the environment.

In exercising its powers under the Act, the National Biosafety Management Agency, developed the National Biosafety Guidelines on Gene Editing 2020, which makes provisions guiding stakeholders, applicants, and the general public, on applications for gene editing, highlighting the application procedure and the NBMA's oversight activities on gene editing. The National Biosafety guidelines are confusing as it relates to human genome editing. There is no specific reference to humans, but it provides that it is applicable to "living organisms". Will it be appropriate to stretch the meaning of "living organisms" to include human being?

7.0 Regulating Human Genome Editing in the United Kingdom

Regulating biomedical research in the UK is subject to both national legislations and a number of international obligations⁵⁹. These are outlined below:

7.1 National Legislation

The Human Fertilisation and Embryology Act 1990 established the Human Fertilisation Embryology Authority, which is responsible for regulating fertility clinics, the treatment and research involving human egg and sperm cells, and human embryos outside of the body.⁶⁰ The HFE Act, amended, prohibits all activities, outside the body, involving human embryo, unless a licence has been previously obtained. A list of activities for which licences may be obtained, is contained in Schedule 2 of the Act. However, Part 2 of the Mitochondrial Donation Regulations 2015, makes provisions for exceptions to this rule. The legislation provides for replacements for mitochondrial DNA, in preventing serious mitochondrial disease.⁶¹ The HFEA has powers to grant licences for creating, keeping or using embryos in any project for which the licence was granted.⁶²

7.2 International Initiatives

International Conventions relevant to research involving hGGE include Declarations on Bioethics and Human Rights, on the Human Genome and Human Rights and on Economic, Social and Cultural Rights. Article 3 (2) of the Universal Declaration on Bioethics and Human Rights⁶³, provides that the interests and welfare of the individual should have priority over science or society. By virtue of Article 4, the benefits of

⁵⁹ Nuffield Council on Bioethics (2018). Genome Editing and Human Reproduction. 183. Nuffield Council on Bioethics. See also Yotova, R. (2017). The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative Law. 61. Nuffield Council on Bioethics.

⁶⁰ Section 5 Human Fertilisation and Embryology Act 1990.

⁶¹ Part 2. Parliament UK (2015). The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015.

⁶² See Schedule 2 of the Act.

⁶³ SHS/EST/BIO/06/1, SHS.2006/WS/14

the procedure should outweigh the risks. Article 16 in its part, states that the impact of life sciences on future generations, including on their genetic constitution, should be considered seriously. By virtue of Article 20, all risks related to medicine, the life sciences and associated technologies should be assessed and managed.

In addition, Article 5 (a) states that ahead of conducting research, treatment or diagnosis affecting an individual's genome, an assessment of the potential risks and benefits involved should be undertaken, in compliance with national laws. Article 10 makes provision for upholding human rights, freedoms and dignity of individuals or groups of people, in the conduct of human genome editing. The main purpose of carrying out human genome research and its application, shall be for the purpose of promoting relief from suffering and improving health of individuals and humankind.⁶⁴

Other relevant international initiatives include, Art. 12 of the International Covenant on Economic, Social and Cultural Rights⁶⁵ which calls for reducing infant mortality and stillbirth rates, guaranteeing healthy development of children and preventing, controlling and treating diseases, by upholding the right to health.

Another regulatory instrument in the UK is the International Commission on the Clinical Use of Human Germline Genome Editing. This is a 2019 initiative of the UK's Royal Society, the US National Academy of Science and the US National Academy of Medicine⁶⁶. The Commission was set up to develop principles, criteria and standards for the clinical use of genome editing of the human germline, in anticipation of the acceptance of human germline. In the UK, genome editing for reproductive purposes is currently unlawful.

⁶⁴ Art. 12(b) Universal Declaration on Bioethics and Human Rights

⁶⁵ United Nations, Treaty Series, vol. 993, p. 3

⁶⁶ POST No.611. p.2

8.0 Regulating Human Genome Editing in the USA

In the United States, human genome editing is treated as biological drug and device, by the Federal Drug Authority (FDA). Applying gene editing in treating diseases such as haemophilia, sickle cell anaemia and some forms of cancer are permitted. In the USA, there has been a call for consensus on the issue of human genome editing. This call is based on the fact that, disparities will result in people travelling to countries with less stringent regulations and policies on human genome editing. A situation known as “ethics dumping”.⁶⁷

The WHO in its part, inaugurated the Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing. This Committee has developed principles for setting up strong human genome editing governance frameworks, which are flexible bearing in mind that one size caps do not necessarily fit all, globally. In formulating national governance frameworks, consideration should be had for the potential benefits of somatic cell editing.

9.0 Socio-Cultural Relativism in Genome Editing

Gene editing is as much a socio-cultural issue as it is a medical procedure. This is because human beings are considered to be ‘social animals.’ One notable reference is Aristotle's Politics, where he stated that “man is by nature a social animal.”⁶⁸ This idea has been further developed and studied by other social psychologists.⁶⁹ In addition, According to Article 1 of Universal Declaration on the Human Genome and Human Rights, the human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity, thus it is the heritage of humanity.⁷⁰ This

⁶⁷ Global ethical principles will prevent unethical researchers from moving to whichever country that has the loosest regulations.

⁶⁸ Durkheim, E. (1951). *Suicide: A Study in Sociology*. New York: Free Press.

⁶⁹ Baumeister, R. F., & Leary, M. R. (1995). The Need to Belong: Desire for Interpersonal Attachments as a Fundamental Human Motivation. *Psychological Bulletin*, 117(3), 497-529.

⁷⁰ Article 1, Universal Declaration on the Human Genome and Human Rights

underscores the importance of human genome as a focal point in socio-cultural discuss.

The theory of Cultural relativism posits that ethical and social standards are reflective of the cultural context from which they originate. It states that cultures are fundamentally different, and so also are the moral frameworks that regulate relations within different societies.⁷¹ Cultural relativism is the view that ethical and social standards reflect the cultural context from which they are derived. Cultural relativists uphold that cultures are fundamentally different from one another, and so do the moral frameworks that assemble relations within different societies.⁷² In international relations, cultural relativists determine whether an action is 'right' or 'wrong' by evaluating it according to the ethical standards of the society within which the action occurs.⁷³ This means that one culture's values, beliefs, and practices cannot be judged by the standards of another culture, as each culture has its own unique history, traditions, and norms. What actually binds people together is their culture, their ideas and their standards⁷⁴ Cultural relativism suggests that no culture is inherently superior or inferior to another, and that each culture should be respected for its own unique contributions to the world. This approach encourages people to be liberal and sympathetic of cultural differences, rather than making judgements based on their own cultural biases. Ruth Benedict explores the idea that different cultures have unique patterns of behaviour and values that should be understood in their own context.⁷⁵ Cultural relativism has also been used

⁷¹ Carnegie Council for Ethics in International Affairs -Cultural Relativism 2023 <https://www.carnegiecouncil.org/explore-engage/key-terms/cultural-relativism#:~:text=Cultural%20relativism%20is%20the%20view,structure%20relations%20within%20different%20societies>.

⁷² Carnegie Council for Ethics in International Affairs -Cultural Relativism 2023 <https://www.carnegiecouncil.org/explore-engage/key-terms/cultural-relativism#:~:text=Cultural%20relativism%20is%20the%20view,structure%20relations%20within%20different%20societies>.

⁷³ Ibid.

⁷⁴ Benedict Ruth 1934, *Patterns of Culture: An Enduring Classic* (1934) Routledge p11

⁷⁵ ibid

to promote human rights and social justice, as it recognises the importance of cultural diversity and the need to protect the rights of minority cultures.⁷⁶ There are diverse views and perspectives on the use of Genome Editing and each viewpoint is dependent on the position of the individual either as a patient, caregiver, relatives and family members of patients and general members of the society or public.⁷⁷ For instance, patients with genetic disorders or their caregivers may view genome editing as a hopeful avenue for developing new therapies or cures, while others may worry about the safety and long-term effects of such interventions. In the same way, scientists and researchers may see genome editing as a tool for advancing knowledge and understanding of biological systems, but members of the general public may have concerns about the implications of altering the genetic makeup of living organisms. Members of the general public may have varying opinions on genome editing depending on their level of knowledge and awareness about the technology. Some may see it as a groundbreaking advancement in science and medicine, while others may view it with suspicion and fear, worrying about potential misuse or unintended consequences.⁷⁸ As such, it is important to engage in informed and respectful discussions about the use of genome editing, taking into account the various perspectives and concerns of different stakeholders. This can help to promote transparency, collaboration, and responsible decision-making in the development and implementation of genome editing technologies. Genome editing is not a well-won debate and it is still contentious. Some people view it as a promising technology that could revolutionize medicine and improve human health, while others

⁷⁶ United Nations. (2016). Declaration on the Rights of Indigenous Peoples. Retrieved from <https://www.un.org/development/desa/indigenouspeoples/declaration-on-the-rights-of-indigenous-peoples.html>

⁷⁷ National Academy of Sciences, Engineering, and Medicine. (2017). Human genome editing: science, ethics, and governance. Washington, DC: The National Academies Press.

⁷⁸ Center for Genetics and Society. (2020). Human gene editing: perspectives, risks, and regulation. Retrieved from <https://www.geneticsandsociety.org/internal-content/human-gene-editing-perspectives-risks-and-regulation>.

have concerns about its safety, ethical implications, and potential misuse.

Overall, the use of genome editing raises complex ethical and societal issues that require careful consideration and discussion among all stakeholders, including scientists, medical experts, legal practitioners, policymakers, and the public.

Taking a cue from and considering the challenges of recent times on other medical procedure like sex change and transgender procedure which has generated different and unintended consequences where experts are being queried on viability and legality of their action. For instance, recently a young de-transitioned woman has made claims against doctors stating that they failed her after her breasts and uterus were removed when she thought she was a man during mental health crisis.⁷⁹ She is suing all the eight health care workers who helped her in facilitating her transition. In that case one Michelle Zacchigna, 34, brought an action against the doctors and mental health professionals that managed her testosterone treatments and administered a bilateral mastectomy and hysterectomy, to her, during her alleged mental health crisis period. Over a ten-year period, she consulted with therapists, including a hormone therapist, having minimal contact with them. She claimed that her interaction with one of them lasted under an hour. In that 10 year period, she also underwent irreversible surgery, while a diagnosis of mental health condition would have been more appropriate in her situation. Zacchigna alleged that the health professionals failed to address her mental health needs, instead she underwent irreversible procedure to her body, thereby suppressing feminine characteristics with testosterone. She noted that,

⁷⁹ James Reynolds 2023, Mail Online, https://www.dailymail.co.uk/news/article-11780709/De-transitioned-woman-sue-doctors-removed-uterus-mental-health-crisis.html?ito=native_share_article-nativemenubutton

*I will live the rest of my life without breasts, with a deepened voice and male-pattern balding, and without the ability to get pregnant. Removing my completely healthy uterus is my greatest regret.*⁸⁰

This is a typical example of the long-term effect of irreversible medical procedure. Such procedure calls for caution and utmost restraint especially when the consequences are irreversible. It can lead to avoidable plethora of cases which would further stifle the development of medical science.

To further buttress the conflicts against natural order of gene modification; the celebrated case of the Chinese scientist is a classic example. The Chinese scientist He Jiankui claimed to have created the world's first genetically edited babies. He Jiankui announced in November 2018 that he had used CRISPR gene-editing technology to modify the genes of two embryos before implanting them in the mother's womb. The twins, known by their pseudonyms Lulu and Nana, were reportedly born healthy, but the announcement of their birth was met with international condemnation and He Jiankui was widely criticized for his actions.⁸¹ After a public outcry, Chinese authorities launched an investigation into Jiankui's work and found that he had violated Chinese national regulations and ethical principles. According to state media reports, Jiankui's experiments resulted in the birth of twin girls whose DNA he had edited to make them resistant to HIV. Jiankui was subsequently sentenced to three years in prison and fined three million yuan (about \$430,000) in December 2019 for "illegally carrying out the human embryo gene-editing intended for reproduction." The controversial experiment carried out by this scientist raised serious

⁸⁰ Supra.

⁸¹ Echo Xie, 2023 'He Jiankui, Chinese creator of world's first gene-edited babies, cancels Oxford event'.
https://www.scmp.com/news/china/science/article/3210191/chinese-creator-worlds-first-gene-edited-babies-drops-out-oxford-event-amid-concern-over-lack?utm_source=email&utm_medium=share_widget&utm_campaign=3210191

ethical and socio-cultural concerns about the implications of gene editing and the potential consequences of such technologies. It also led to renewed calls for tighter regulations and proper legal framework for the use of gene-editing technology in humans.⁸²

Thus, the creation of the so-called ‘designer babies’ is seemingly an affront against natural order where a scientist decided to ‘play’ God in the manipulation of genes to create HIV-free twin babies.

Summarily, some of the identifiable cultural issues associated with both somatic and germline genome editing are as follows:

1. Safety: Genome editing technologies can cause unintended changes to the genome, leading to unforeseen consequences and potential harm to the individual or future generations.
2. Equity: Access to genome editing technologies may be limited to certain populations, raising concerns about fairness and exacerbating existing health disparities. Indigent population may never be able to afford this procedure and this would make it inaccessible to such category of persons.
3. Autonomy: Decisions about whether to undergo genome editing should be made by the individual, with informed consent and without coercion. This is further elaborated under body autonomy.
4. Justice: Germline genome editing raises questions about the creation of "designer babies" and the potential for exacerbating existing social and economic inequalities. The hallmarks of a balanced society are equity, justice and fairness and the absence of the which can have serious consequences.
5. Religious and Cultural beliefs: Genome editing raises questions about cultural beliefs and values surrounding the sanctity of human life, the role of genetics in human identity, and the boundaries of what is considered natural or acceptable. Genome

⁸² Supra.

editing may also be viewed differently across different religious groups. Some may view it as God's provision and way to cure genetic diseases, while others may view it as interfering with nature or playing God.⁸³

6. Legal Consequences: The use of genome editing technologies could also have legal implications related to liability, ownership of genetic material, and patentability.⁸⁴
7. Regulatory frameworks: The development and use of genome editing technologies will require regulation in order to ensure its safety and effectiveness. There may be differences in how different countries approach the regulation of genome editing, which could create issues related to international collaboration and standardisation.⁸⁵

Overall, the ethical and cultural issues surrounding human genome editing are complex and multifaceted, and require careful consideration and discussion to ensure that the technology is developed and used in a responsible and ethical manner.

10 Body Autonomy and the Incursion of Genome Editing

The impact of medical interventions rarely affects others, but the individual on who they were performed.⁸⁶ With heritable human genome editing, the impacts transcend the generation on who the procedure was performed. This has provided parents whose children are at risk of having heritable diseases with the option of taking the risk of undergoing heritable genome editing. The issue raised by this

⁸³ Caulfield, T., Murdoch, C. J., & Rao, A. (2018). Representations and Realities of Genome Editing: A Critique of the Social and Ethical Implications Literature. *New Genetics and Society*, 37(4), 333-350.

⁸⁴ UNESCO International Bioethics Committee. (2015). Report of the IBC on Updating Its Reflection on the Human Genome and Human Rights. Paris: UNESCO.

⁸⁵ National Academies of Sciences, Engineering, and Medicine. (2017). *Human Genome Editing: Science, Ethics, and Governance*. Washington, DC: The National Academies Press.

⁸⁶ An exception is the effect of Thalidomide on unborn children.

possibility, is hinged on the determination of who should be the deciding authority/personality. Should it be the concerned parents or the society? In addition, the extent of permissibility required, needs to be ascertained.

Another area of concern is that the level and condition of acceptability of heritable human genome editing, differs from country to country, with a resulting divergence of policy responses. There is also no certainty on where a balance can be placed, bearing in mind that, the ability to strike a balance is key to regulating human genome editing. This can only be determined by the values of a given society, vis – a vis implementation of their laws, as it relates to technology.

A crucial factor in this discussion is the issue of autonomy. This ethical principle plays an important role in striking a balance between the rights and duties of the individual and the society, and in some cases, that of the international community. The concept of proportionality has been developed, as a tool for striking this desired balance. In international law, the concept of Proportionality, states that,

the legality of an action shall be determined depending on the respect of the balance between the objective and the means and methods used as well as the consequences of the action.⁸⁷

The application of this concept, requires States to their restrictive regulations. This can be difficult to discharge, given the scientific uncertainties that germline editing is characterized with. The principle of primacy of the human being in biomedicine was established by the

⁸⁷ The Practical Guide to Humanitarian Law. A publication by *Medicins sans Frontieres*. <https://guide-humanitarian-law.org/content/article/3/proportionality/#:~:text=Proportionality%20is%20a%20core%20principle,the%20consequences%20of%20the%20action.>> Accessed on 15/4/2023

Oviedo Convention⁸⁸ and the UNESCO Declaration on Bioethics and Human Rights. The implication of this is that in balancing individual rights with those of society and science, the interest and welfare of the individual is of utmost priority.⁸⁹ In all these, the rights of the embryo cannot be ignored. Cognisance must be taken of the rights of the embryo and issues raised in recognising these rights.

11 Summary and Conclusion

Human genome editing, no doubt, is a beneficial development in biomedicine. It is a known fact that genome editing techniques, such as CRISPR-Cas9, are of great value to transforming and advancing medicine. Their application has however proved to be a stress test to existing legal framework. It is therefore pertinent to develop a lasting and acceptable solution to preventing its misuse.

As noted in this paper, a total and general ban of its application, will deprive people from benefiting from using it for preventive and curative medicine.⁹⁰ There is therefore a need for effective regulation of its use. In doing this, the various ethical and legal concerns, exhibited, should be considered.

Globally, there is an indication of a consensus that human genome editing should be undertaken, mainly, for preventive, therapeutic and diagnosis purposes, but its use for reproductive purposes, should be restricted.

⁸⁸ The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No 164) was opened for signature on 4 April 1997 in Oviedo (Spain). A Convention of the Council of Europe. <<https://www.coe.int/en/web/bioethics/oviedo-convention>> Accessed on 15/4/2023.

⁸⁹ Różyńska, J. Taking the principle of the primacy of the human being seriously. *Med Health Care and Philos* 24, 547–562 (2021). <https://doi.org/10.1007/s11019-021-10043-2> on 14/4/2023

⁹⁰ Slokenberga, S., Minssen, T., Nordberg A., 2022. Governing, Protecting, and Regulating the Future of Genome Editing: The Significance of ELSPI Perspectives. *European Journal of Health Law* 29, 327–340

Furthermore, it is agreed that, human genome editing for clinical and research purposes, should observe ethical principles, such as respect human dignity and other human rights. In doing this, the risk benefit ratio must be considered. The risk of human genome editing, must therefore not be disproportionate to the potential benefits. Risk assessment and management are therefore essential in carrying out the procedure. Also important is the need for strict compliance to the informed consent requirement.

The paper concludes by making a call for effective regulation of the use of the human genome editing technique in therapeutic, preventive and diagnosis practice, as well as for reproductive purposes.

12 Recommendations

It is pertinent to understand global policy landscape, in discussing human genome editing governance, bearing in mind that, some nations do not have any legal framework in place.⁹¹

The use of international law in regulating human genome editing, will be an appropriate format for managing these techniques, because it has been able to develop tools which can be use to strike an appropriate balance between the various interests. It is useful in regulating activities of both States and non-State actors across national borders. International laws can be used to harmonise domestic laws. It is therefore recommended that, given the speed of technological advancement, as a matter urgency, the recommendations of the Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing, in relation to the ethical,

⁹¹ Baylis, F., Darnovsky, M, Hasson, K & Timothy M. 2020. Human Germline and Heritable Genome Editing: The Global Policy Landscape. The CRISPR Journal Volume 3, Number 5,

legal and social challenges associated with human genome editing, be adopted, globally. The committee set up by the WHO.⁹²

The committee, amongst others, recommended that, a registry be set up⁹³, using the International Clinical Trials Registry Platform⁹⁴, for the purpose of improving data collection for human genome editing; genetic manipulation should be strictly prohibited for reproductive purposes, with punitive measures attached to violations; and the prohibition of the dealing in human ova, sperm, embryos or fetal tissues for gene manipulation.

This paper strongly recommends enacting legislations that will ensure safety and efficacy challenges, can be and have to a considerable extent, been resolved. Consequently, governance frameworks which incorporate fundamental values and principles, should be put in place. This governance framework should consider and address existing challenges and uncertainties.

Finally, this paper recommends continuous oversight for monitoring and reviewing system of embryonic stem cell researches, and the establishment of an effective traceability and liability system. Nonetheless, in the absence of effective liability and traceability system, this cannot be achieved.

⁹² WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing. Human Genome Editing: position paper. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

⁹³ Owoseye, A., 2019. Who Introduces Global Registry On Human Genome Editing? Retrieved 12 April, 2023 from <https://www.premiumtimesng.com/news/more-news/349626-who-introduces-global-registry-on-human-genome-editing.html?tztc=1>

⁹⁴ WHO announced plans for an initial phase of the registry using the International Clinical Trials Registry Platform (ICTRP), a WHO entity, the committee called on all relevant research and development initiatives to register their trials.