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LEGAL AND ETHICAL CONSIDERATIONS FOR HUMAN GENE EDITING IN INDIA

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ABSTRACT

Recent advances in biotechnology have created new opportunities for biomedicine, particularly in the area of human gene editing. Yet, the legal and ethical ramifications of gene editing technology in human genome research have sparked heated controversy. Since there are no worldwide treaties or covenants that govern human gene editing on a global scale, several countries have formed their own domestic legal framework to oversee these technologies. Human gene editing technology has huge potential benefits but it also carries a lot of risks. The formation of legal and policy frameworks is critical in setting the boundaries of permissible and prohibited activity in this field. This article provides an overview of the current International debate on the legal and ethical issues surrounding human gene editing, as well as a review of India's legal and policy framework. It also makes recommendations and suggestions for enhancing the national legal and policy framework based on strong ethical and legal foundations.

Key Words: **Human Gene Editing, Gene Editing Technology, CRISPR, Law & Ethics**.

I. INTRODUCTION:

Gene Editing (GE) is the process of changing the genome by adding, cutting, removing, or altering base pairs of DNA with molecular scissors. Scientists have been experimenting with editing methods on humans for the last few years in an effort to get rid of damaging mutations or undesired genes that are responsible for a number of hereditary diseases or ailments. This technique has a huge upside because it makes search-and-replace and accurate copy-and-paste options possible. Since 2013, there have been several quick developments in this field, with applications in a wide range of fields including drug discovery, gene therapy,

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animal studies, genetic variation, fuels, and food etc. The development of disease models and therapeutic applications has advanced via basic and applied research in various biological systems of plants and animals.

There are several methods for Gene Editing, including *"Zinc Finger Nuclease (ZFN)"* and *"Transcription Activator Life Effector Nuclease (TALEN)"*, which can offer wide therapeutic potential.[1] However, ***"Clustered, Regularly, Interspaced, Short Palindromic Repeat (CRISPR/Cas9)"*** has been discovered by many to be relatively economical, easy, time efficient, and also has a better degree of precision. CRISPR/Cas9 technology efficiently and precisely edits DNA and modifies genes, potentially curing numerous genetic illnesses. The "Cas9" protein, operating as a pair of scissors, unzips DNA using CRISPR technology. Both *"in-vitro"* and *"in-vivo"* systems have been used to test this quick and effective technique.

Although human gene editing technology (HGET) appears to be straightforward and has great promise for finding a treatment for several diseases, there is also the possibility for misuse, which can lead to unethical and contentious results. Contrary to other techniques, CRISPR has the potential to pass on genetic alterations to the future generation.[2] As a result, the use of Gene Editing tools is limited to somatic cells or adult cells that are not intended for reproduction. Gene Editing has been regulated or even outrightly banned in several countries due to the potential threat it poses.[3]

Since India has a massive burden of unmet medical demands and genetic abnormalities, gene therapy may be useful in this area. However, it also entails technological dangers and moral dilemmas. Dr. He Jiankui, a Chinese scientist from the "Southern University of Science and Technology in Guangdong, China", created babies using Germ-line Gene Editing on

[1] Indian Council of Medical Research (ICMR), "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017", (2018), available at: https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last visited on August 25, 2020).

[2] Dong S, Lin J, Held NL, et.al.,, "Heritable CRISPR/Cas9-mediated genome editing in the yellow fever mosquito, Aedesaegypti" 1–13, 10(3) PLoSOne (2015).

[3] Howard HC, Van EL CG, et.al., "One small edit for humans, one giant edit for humankind? Points and questions to consider for a responsible way forward for gene editing in humans" 1-11, 26(1) European Journal of Human Genetic (2018).

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November 26, 2018[4], which drew criticism from all over the world and ultimately sparked a discussion about the moral and legal implications of using gene therapy technologies. He Jiankui asserted that the use of "CRISPR/Cas9" technology enabled him to have two babies who were HIV/AIDS resistant. This was also presented at the Hong Kong *"Second International Summit on Human Genome Editing, 2018"*. It also highlighted the need for strict norms and restrictions to stop abuse and premature commercialization.[5]

II. INTERNATIONAL PERSPECTIVE:

Human Gene Editing (HGE) is a topic that has received a lot of attention on a global scale. The use of gene editing tools like CRISPR/Cas9 in humans has the potential to change the way of medical treatment and enhance the quality of life for millions of people. However, it also brings up significant ethical and legal issues that require attention. The need for regulating HGE has been acknowledged by the International community, which has proposed a number of declarations and agreements to direct the research and use of this technology.

One of the major concerns with HGE is the potential for risk and injury to individuals. Another crucial factor to consider is the informed consent of research participants. The *"Nuremberg Code, 1947"*, enacted in response to Nazi doctors' atrocities during WWII, established the concepts of informed consent and voluntary involvement in research.[6] The *"Helsinki Declaration"*, which was later developed in 1964, reaffirmed the need for informed consent and emphasised the importance of researchers completely informing participants about the nature, purpose, dangers, and potential benefits of the research.[7] These

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[4] Marilynn Marchione, "Chinese researcher claims first gene-editing babies", AP News, November 26, 2018, available at <https://apnews.com/article/ap-top-news-international-news-ca-state-wire-genetic-frontiers-health-4997bb7aa36c45449b488e19ac83e86d> (last visited on August 24, 2020).

[5] *Ibid.*

[6] The Nuremberg Code, 1947, *In Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10 (United States vs. Karl Brandt et. al.),* Washington, US, Government Printing Office, 2 (1949) 181-182, *available at:* https://research.unc.edu/human-research-ethics/resources/ccm3_019064/ (last visited on August 25, 2020).

[7] WMA Declaration of Helsinki: Ethical Principles for Medical Research involving Human Subjects, 1964 (World Medical Association), *available at:* https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principle-for-medical-research-involving-human-subjects/ (last visited on August 25, 2020).

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concepts have been strengthened in more recent treaties and conventions such as the *"Universal Declaration on the Human Genome and Human Rights, 1997"*, "*International Declaration on Human Genetic Data, 2003", "The Universal Declaration on Bioethics and Human Rights, 2005", " The United Nations Declaration on Human Cloning, 2005"*[8], *"International Summit on Human Gene Editing, 2015", and "The Second International Summit on Human Genome Editing, 2018".*

Also, there are worries about technological abuse, privacy invasion, and confidentiality breaches that are needed to be taken seriously in order to stop the stigmatisation of the participants. Thus, it becomes vital to put in place guidelines for safety precautions and sufficient protections for each person's privacy, dignity, and human rights. The importance of preserving individual privacy, dignity, and human rights is emphasised by several declarations such as: *"The Universal Declaration of Human Rights, 1948", "The International Covenant on Civil and Political Rights, 1966"*, and *"The Convention on the Rights of Persons with Disabilities (CRPD), 2006".*

The *"Universal Declaration on the Human Genome and Human Rights, 1997"* is a significant declaration that emphasises the ethical, legal, social, and economic consequences of human genome research. The declaration acknowledges the great potential of research into the human genome and the applications that come from it for enhancing the health of both individuals and humankind as a whole. However, it also emphasises that such research must adhere to the complete respect for human dignity, freedom, and rights, as well as the prohibition of all types of genetic discrimination.[9]

[8] United Nations, "General Assembly Adopts United Nations Declaration on Human Cloning by Vote of 84-34-37", March 8, 2005, *United Nations Press*, *available at* <https://press.un.org/en/2005/ga10333.doc.htm> (last visited on December 30, 2020).

[9] Universal Declaration on the Human Genome and Human Rights, 1997.

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A multidisciplinary expert advisory group entitled: *"The Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing",* was established by the World Health Organization (WHO) in December 2018 to address this problem. Experts from all over the world make up the group, which will make recommendations on a number of topics relating to HGE, such as the ethics of germline editing, the regulation of clinical trials, and the administration of HGE research.[10]

In addition to International laws, there have been worldwide efforts to regulate HGE. Given that recent scientific and technical advances have pushed humanity far closer to the ability to genetically modify future humans and edit out diseases, there is an urgent need for effective regulation of the human genome and genetic interventions in both International and domestic legal regimes. Future legislation would need to specify general guidelines for when and under what conditions human germline modification is to be permitted. There has been a tremendous increase in scientific knowledge in the area of human genetics, which has increased the need to investigate regulatory possibilities and determine whether the lack of consensus still remains. Since there are no treaties or conventions that govern HGE on a global scale, several countries have formed their own domestic legal framework to oversee these technologies.

In the United Kingdom (UK), "The Human Fertilisation and Embryology Act, 1990" (hereinafter to be referred as HFE Act) established the "Human Fertilisation and Embryology Authority (HFEA)" as the independent governing authority in the UK for reproductive clinics, treatments, and studies using human sperm, egg, and embryos outside the body. The amended HFE Act makes all activities with human embryos outside the body illegal unless permitted.[11] The activities for which licenses may be granted are listed in Schedule 2 to the Act which includes treatment and research. A treatment license cannot be used to alter the DNA of a cell while it is still part of an embryo, according to Schedule 2.[12]

The United States (US) does not outrightly prohibit gene editing but it does place restrictions on financing for research that involves embryos in general and particularly gene editing of

[10] World Health Organization, *WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing*, 2019, *available at* <hhttps://www.who.int/publications/i/item/WHO-SCI-RFH-2019-02> (last visited on September 24, 2020).

[11] The Human Fertilisation and Embryology Act, 1990.

[12] *Id.,* sch 2.

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embryos. State support of research involving human embryos is prohibited under the US law, that: *"1) the creation of a human embryo or embryos for research purposes; or 2) destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on foetuses in utero".*[13] As a result, the question of whether research employing gene editing may be sponsored by the US would entail determining whether it would amount to deliberately exposing the embryo to a larger risk of injury or death than that authorised for *in-utero* research.

In Australia, "The National Health and Medical Research Council (NHMRC)" has established guidelines on HGE, emphasising the importance of carefully considering the ethical and societal consequences of this technology.[14] The "Prohibition of Human Cloning for Reproduction Act, 2002" in Australia makes heritable genome alteration a criminal offence, which states that: *"A person commits an offence if the person alters the genome of a human cell in such a way that the alteration is heritable by descendants of the human whose cell was altered; and in altering the genome, the person intended the alteration to be heritable by descendants of the human whose cell was altered."*[15]

In Canada, Human gene editing is subject to rigorous rules. The "Assisted Human Reproduction Act", which was introduced by the Canadian government in 2004, prohibits the genetic manipulation of human embryos intended for reproduction.[16] This includes any genetic modification that might be passed on to subsequent generations, barring therapeutic uses to treat a significant medical problem.[17] Furthermore, the Canadian government has established the Council of Canadian Academies to provide expert guidance on developing scientific and technical challenges, such as HGE. The Council released a report in 2020 on the possible effects of HGE such as access and affordability challenges. The report emphasised the importance of thorough public consultation and careful assessment of ethical,

[13] Dickey-Wicker Amendment, 1996, s. 509(a).

[14] National Statement on Ethical Conduct in Human Research, 2018.

[15] Prohibition of Human Cloning for Reproduction Act, 2002.

[16] Assisted Human Reproduction Act, 2004.

[17] *Ibid.,* Sec. 5 (1): *"alter the genome of a cell of a human being or in vitro embryo such that the alteration is capable of being transmitted to descendants."*

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legal, and social issues.[18] In general, Canada has been cautious when it comes to HGE, putting peoples safety and well-being as well as the welfare of society at first. The nation has acknowledged the need for ethical and legal standards to control the use of this technology and safeguard human rights.

Although there is an increasing consensus that HGE has to be regulated, there are worries about the efficiency of current restrictions and the possibility that this technology may be utilised for unethical objectives. A Chinese scientist sparked outrage in 2018 when he said that he had developed the world's first genetically altered infants using CRISPR-Cas9 technology.[19] He Jiankui, a scientist, received harsh criticism for defying ethical and scientific standards and was ultimately given a three-year prison sentence. The People's Republic of China thankfully promulgated *"The Regulation of the People's Republic of China on the Administration of Human Genetic Resources"* on May 28, 2019, with the intention of safeguarding public interest, national security, and health through effective management and use of China's human genetic resources.[20]

Despite the fact that HGE has enormous potential to improve human health and well-being, it is crucial that this technology be regulated in a way that promotes safety, equity, and respect for human rights. In order to direct the development and application of HGET, the International community has recognised the significance of addressing these concerns and has proposed a number of declarations and agreements. As this technology advances, it will be vital to have open, transparent, and inclusive dialogues to ensure that it is used responsibly and for the benefit of all.

III. INDIAN PERSPECIVE:

The arena of '**DNA**' research has changed dramatically in the last few years with the development of new methods of HGE like CRISPR/Cas9, TALEN, ZFN, etc. These techniques offer enormous opportunities for benefit from science; yet proper legal and ethical guidelines are very much essential to utilize it in a responsible and safer manner. In India,

[18] Council of Canadian Academies, *The Expert Panel on the Approval and Use of Somatic Gene Therapies in Canada*, 2020, available at <https://cca-reports.ca/reports/somatic-gene-and-engineered-cell-therapies/>

[19] Marilynn Marchione, "Chinese researcher claims first gene-editing babies", AP News, November 26, 2018, available at <https://apnews.com/article/ap-top-news-international-news-ca-state-wire-genetic-frontiers-health-4997bb7aa36c45449b488e19ac83e86d> (last visited on August 24, 2020).

[20] Shuang Liu, "Legal Reflections on the case of genome-editing babies", 5 *Global Health Research and Policy* 24 (2020), *available at* <https://doi.org/10.1186/s41256-020-00153-4> (last visited on August 17, 2020).

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Gene Editing Technology (GET) and its various outcomes are mainly administered by the *"Rules for the manufacture, use, import, export and storage of hazardous micro-organisms, genetically engineered organisms or cells, 1989"*(known as Rules, 1989) notified under the *Environment (Protection) Act, 1986*. These Rules, along with guidelines are implemented by six competent authorities under the "Department of Biotechnology", "Ministry of Environment, Forest and Climate Change" and the various State Governments.[21]

The scope of Biomedicine in India mainly revolves around the Indian Council of Medical Research (ICMR), the Department of Biotechnology (DBT), and the Central Drug Standards Control Organization (CDSCO) Guidelines. The Department of Biotechnology (DBT) has undertaken to update the existing guidelines namely: *"Recombinant DNA Safety Guidelines, 1990"* and "*Revised Guidelines for Safety in Biotechnology, 1994"* in the areas of bio-safety. Through intense National and International consultations and inputs from the various stakeholders, the DBT initiated new guidelines titled: "*Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017".*[22] These new guidelines supersede and replace the earlier guidelines mentioned above. These include a whole range of research, laboratory use, import/export, storage and handling, manufacturing, disposal and emergency procedure, and facility certification.

According to the provisions of the "*Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or*

[21] Murali Krishna Chimata and Gyanesh Bharti, "Regulation of Genome Editing Technologies in India", 28 Transgenic Research 175–181 (2019), available at <https://doi.org/10.1007/s11248-019-00148-z> (last visited on August 24, 2020).

[22] Department of Biotechnology (DBT), "Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017", (April 1, 2018), available at <https://rcb.res.in/upload/Biosafety_Guidelines.pdf> (last visited on August 26, 2020).

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Cells, 1989"[23], all the Institutional Biosafety Committees (IBSC's) and the host institutions who are responsible with regards to research and development of Genetically Engineered Organisms are required to comply with the "*Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017"* and non-compliance shall attract the penal provisions of Section 15 (Penalty for contravention of the provisions of the Act and the rules, orders and directions), Section 16 (Offences by Companies) & Section 17 (Offences by Government Departments) of the *Environment (Protection) Act, 1986.*[24]

Recently, ICMR, DBT & CDSCO co-jointly framed the *"National Guidelines for Gene Therapy Product Development and Clinical Trials (2019)."*[25] The "Central Drugs Standard Control Organization (CDSCO)" notified the "*The New Drugs and Clinical Trials Rules, 2019*"[26] where the "Gene Therapy Product" has been specified as the "New Drug."

Apart from that there are other legal and policy frameworks in India that basically address the legal and ethical issues surrounding the research in the field of Human Gene Editing, such as: *"National Ethical Guidelines for Biomedical and Health Research Involving Human*

[23] Ministry of Environment & Forests, "Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or Cells, 1989", (December 5, 1989), available at <https://ibkp.dbtindia.gov.in/DBT_Content_Test/CMS/Guidelines/20181115121526033_Rules-for-the-manufacture-use-import-export-and-storage-1989.pdf> (last visited on August 26, 2020).

[24] The Environment (Protection) Act, 1986, India, available at: https://ibkp.dbtindia.gov.in/DBT_Content_Test/CMS/Guidelines/20181115121450052_The-Environment-Protection-Act-1986.pdf (last visited on August 26, 2020).

[25] Indian Council of Medical Research (ICMR), Central Drugs Standards Control Organisation (CDSCO) & Department of Biotechnology (DBT), "National Guidelines for Gene Therapy Product Development and Clinical Trials, 2019", (November, 2019), available at <https://main.icmr.nic.in/sites/default/files/guidelines/guidelines_GTP.pdf> (last visited on August 25, 2020).

[26] Ministry of Health & Family Welfare, Government of India, "The New Drugs and Clinical Trials Rules, 2019", (March 19, 2019), available at <https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf> (last visited on August 26, 2020).

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Participants, 2017"[27], *"National Guidelines for Stem Cell Research, 2017"*[28], *"National Ethical Guidelines for Biomedical Research Involving Children, 2017"*[29], "*The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945"*[30].

These national guidelines/laws specifically deal with safeguards, directives, ethical issues, and technical challenges that need careful consideration before research on Human Gene Editing takes place.

IV. ETHICAL CONCERNS:

Every new technology must guarantee larger benefits over minimal hazards while bearing in mind the well-being of all living things to attain high success rates. There are several ethical concerns with Human Gene Editing Technology that need to be resolved at the policy level, which are:

i. The Precautionary Principle: The "Precautionary Principle" is a key idea in International Law that has been enshrined in a number of International treaties, including *"The Rio Declaration on Environment and Development"*, *"The Cartagena Protocol on Biosafety"*, and *"The Convention on Biological Diversity"*. According to the principle,

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[27] Indian Council of Medical Research (ICMR), "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017", (2018), available at <https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf> (last visited on August 25, 2020).

[28] Indian Council of Medical Research (ICMR) & Department of Biotechnology (DBT), "National Guidelines for Stem Cell Research, 2017", (October, 2017), available at <https://main.icmr.nic.in/sites/default/files/guidelines/Guidelines_for_stem_cell_research_2017.pdf> (last visited on August 25, 2020).

[29] Indian Council of Medical Research (ICMR), "National Ethical Guidelines for Biomedical Research Involving Children, 2017", (October, 2017), available at <https://main.icmr.nic.in/sites/default/files/guidelines/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children_0.pdf> (last visited on August 26, 2020).

[30] Ministry of Health & Family Welfare, Government of India, "The Drugs and Cosmetics Act and Rules', (April 10, 1940), available at <https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf> (last visited on August 26, 2020).

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precautions should be taken to avoid injury where there is scientific ambiguity regarding the potential dangers of a certain action.

The "Rio Declaration on Environment and Development, 1992" highlights the value of taking preventative steps when there is a risk of severe or irreparable damage, even when the scientific data is ambiguous. The Rio Declaration's Principle 15 declares that: *"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities· Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation"*[31] .

The *"Cartagena Protocol on Biosafety, 2000"* was adopted with the goal of ensuring the safe handling, transportation, and use of living-modified organisms emerging from modern biotechnology. The policy places a strong emphasis on the requirement for preventative steps where there is scientific ambiguity regarding the potential dangers of living modified organisms. In accordance with Article 10 of the Protocol: *"Parties shall consider the need for, and modalities of, a protocol on liability and redress for damage resulting from transboundary movements of living modified organisms, taking into account the objective of the Convention and consistent with the Protocol, as well as other relevant international obligations;"*[32].

The *"Convention on Biological Diversity, 1992"* is an International treaty that aims to protect biodiversity, assure the equitable and fair distribution of the advantages brought about

[31] United Nations Conference on Environment and Development, 1992, pp. 15.

[32] United Nations Cartagena Protocol on Biosafety, 2000, art. 10.

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by genetic resources, and promote the sustainable use of its constituent parts. In the context of contemporary biotechnology, particularly gene editing technologies, the treaty acknowledges the significance of the precautionary principle. According to Article 15 of the convention: *"in the event of lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity, the Party of import, in consultation with the exporter, may take a decision, with appropriate and due regard to the objective of minimizing potential adverse effects on the conservation and sustainable use of biological diversity, to require additional relevant information or impose reasonable conditions."*[33]

The "Precautionary Principle" plays a crucial role in ensuring the safety of human gene editing technology (HGET) research. It emphasizes the need for taking precautionary measures to prevent harm to human health and the environment, in the absence of scientific certainty. The use of HGET involves various risks, and it is essential to assess these risks before conducting research. "The Precautionary Principle" encourages the researchers to consider the risks and benefits of the research and ensure that the potential benefits outweigh the potential harm.

International declarations and conventions, such as *"The Universal Declaration of Human Rights"*[34] and *"The International Covenant on Civil and Political Rights"*[35], recognise the fundamental human right to life, dignity, and health. Therefore, HGET research must be conducted with utmost respect for human dignity and rights. "The Precautionary Principle"

[33] United Nations Convention on Biological Diversity, 1992, art. 15.

[34] Universal Declaration of Human Rights, 1948.

[35] International Covenant on Civil and Political Rights, 1966.

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demands that researchers ensure that the research participants are informed about the possible risks and benefits of HGET and that they provide free and informed consent before participating in research.

Moreover, the "Precautionary Principle" requires researchers to implement adequate measures to safeguard the privacy, confidentiality, and human rights of research participants. In particular, the researcher must ensure that the genetic information of the participants is not misused or used to discriminate against them.

The "Precautionary Principle" underlines the value of taking preventative steps whenever there is a lack of scientific consensus regarding the potential risks of a given course of action. *"The Rio Declaration on Environment and Development", "The Cartagena Protocol on Biosafety",* and *"The Convention on Biological Diversity",* all have provisions that uphold this principle. In the context of contemporary biotechnology, particularly gene editing technologies, these conventions acknowledge the significance of taking precautions to avoid harm.

ii. The Principle of Inter-Generational Equity:

A more recent development in International Law is the "Principle of Intergenerational Equity". It urges States to consider the rights of future generations while carrying out actions that could have an impact on them. The *"Rio Declaration on Environment and Development, 1992"* declares that: *"The right to development must be fulfilled so as to equitably meet developmental and environmental needs of present and future generations".*[36]

In the context of HGE, UNESCO's *"Universal Declaration on the Human Genome and Human Rights, 1997"* highlights the "*Principle of Intergenerational Equity"* by declaring that *"Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted"*[37]. States must take action to prevent

[36] United Nations Conference on Environment and Development, 1992, pp. 3.

[37] Universal Declaration on the Human Genome and Human Rights, 1997, art. 11.

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patenting of procedures that violate human dignity. This proclamation highlights how crucial it is to take into account how genetic changes may affect future generations and how states have a duty to stop actions that can be detrimental to respect for human dignity.

Additionally, the concept is stated in a number of non-binding legal documents, such as the *"UNESCO Declaration on the Responsibilities of the Present Generations Towards Future Generations, 1997"*, which says that: *"The present generations have the responsibility of ensuring that the needs and interests of present and future generations are fully safeguarded"*.[38] Similar provisions on the human gene can be found in Article 6 of the Declaration which states that: *"The human genome, in full respect of the dignity of the human person and human rights, must be protected and biodiversity safeguarded. Scientific and technological progress should not in any way impair or compromise the preservation of the human and other species "*.[39]

In a similar line, Article 16 of the *"UNESCO Universal Declaration on Bioethics and Human Rights, 2005"* declares that States should give adequate consideration to: *"The impact of life sciences on future generations, including on their genetic constitution, should be given due regard."*[40] When it comes to regulating gene editing, the *"Principle of Inter-Generational Equity"* would oblige States to consider the rights of future generations, including the preservation of the human species in its diversity at the very least.

CRISPR/Cas9 germline Gene Editing brings along with the risk of irreparable alterations in the germline like off-targets or faulty gene editing causing serious implications to the future

[38] Declaration on the Responsibilities of the Present Generations Towards Future Generations, 1997, art. 1.

[39] *Ibid.,* art. 6.

[40] Universal Declaration on Bioethics and Human Rights, 2005, art. 16.

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generations. Since there are probabilities of accidental shifts in the germline while conducting the process of gene editing, that could be heritable and may pass on to future generation; therefore even the *'yet to be born or unborn'* future children become the indirect, unknown, and unwilling participants. Thus, while agreeing to this process, an individual is eventually deciding over something serious, on behalf of the entire future generation. Once the genetic changes are made, they would be of permanent nature having long-term effects. Sex determination of a child before its birth has been considered an illegal act in India as per the *"Pre-Conceptions & Pre-Natal Diagnostic Act, 1994 (PNDT)"*[41]; yet many people find out some way or the other to determine pre-natal sex. Also, HGET carries a probability of misuse in the pre-natal examination, thus affecting the sex ratio in India. Moreover, this might lead to unethical foetal manipulations in *In Vitro Fertilization (IVF)* clinics nationwide.

Any alterations introduced within "*Somatic Cells"* limit specifically to the participants only, by not passing on to the upcoming generations. Rare diseases can be treated through the use of somatic cell GE technology. While in the process of safe and efficient methods, there always remains a risk of unexpected *off-target* editing, incidental sequences causing mutations, eventually leading to possible unknown risks. This needs to be carefully evaluated when experiments with human beings are in question. However, looking at the greater prospects, HGET has massive therapeutic potential which can possibly treat rare diseases, making it a significant matter of concern. Over-regulating such a technology might leave the future generation deprived of the benefits that are expected to receive from exploring the field of science and technology.

Overall, the "Principle of Intergenerational Equity" is a significant ethical factor in HGE, and numerous international mechanisms have recognised its importance in ensuring a sustainable and equitable future for all.

iii. The Preventive Principle or No-Harm Principle:

The "Preventive Principle", often referred as no-harm concept, is a cornerstone of environmental ethics and legislation. It asserts that where there is ambiguity about the potential for harm produced by a new technology or product, it is required to take preventive measures to prevent or minimise harm to humans and the environment.

In the context of HGE, the "Preventive Principle" suggests that we should employ gene

[41] The Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994, (Act 57 of 1994), s. 6.

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editing technology with caution until its safety and ethical consequences are well known. Human gene editing technology is still in its early stages, and we are still learning about its potential hazards and benefits.

One significant issue is the potential for unexpected effects of gene editing, such as genetic mutations or off-target impacts. These effects may result into long-lasting and harmful consequences upon people and also the future generations. Consequently, it is crucial to exercise caution and adopt safety precautions in order to avoid or reduce any potential risks associated with gene editing.

The "Preventive Principle", which affirms that States have a duty to ensure that actions under their authority or control do not harm other States, is outlined in Principle 2 of the "*Rio Declaration on Environment and Development*", which provides that: *"States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental and developmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction"*.[42]

The "Preventive Principle" and the requirement for due diligence would call for a high level of prudence prior to applying gene editing for clinical application, including awareness of the factual, scientific, and technological background. Implementing GET would also necessitate stringent regulation of the private sector to ensure that the same high-quality care is applied by all institutions and stakeholders.

iv. The Principle of Impact Assessment:

The "Principle of Impact Assessment" refers to the process of weighing the pros and cons of a certain activity. It is frequently used to make sure that the advantages of a suggested course of

[42] United Nations Conference on Environment and Development, 1992, pp. 2.

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action outweigh its potential drawbacks in areas including environmental policy, economics, and public health.

When it comes to HGE, the "Principle of Impact Assessment" is critical to ensuring that the technology is handled ethically and responsibly. The possible uses of gene editing include the creation of *"designer babies"*, improved human performance, and the treatment of hereditary illnesses. It also brings up important ethical issues of equity, safety, and the possibility of unexpected consequences.

The evaluation of long-term impacts is a crucial part of the "Principle of Impact Assessment" in HGE. There is still little knowledge of the long-term effects of gene editing technologies because they are still in their infancy. For instance, altering a person's genes can have unintended consequences for their offspring or future generations.

The possibility of unexpected consequences is another crucial factor to take into account. Even minor adjustments to the process of gene editing, which involves numerous variables, can have big impacts. For instance, altering a gene to treat one disease may unintentionally raise the risk of another.

Also, the researchers must ensure that they follow up on the participants for a long time to detect any potential adverse effects or genetic disorders that may emerge later. *They must ensure that the research participants are well-informed, and protected, and their human rights are respected. Therefore, researchers must implement adequate safeguards and protections to prevent the misuse of HGET and ensure that it is used for the benefit of society.*

UN Agenda 21 also stressed that: *"There is a Need for further development of internationally agreed principles on risk assessment and management of all aspects of biotechnology …"*[43]

Particularly noteworthy is Article 20 of the *"UNESCO Universal Declaration on Bioethics*

[43] United Nations Conference on Environment and Development, 1992, para. 16.29.

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and Human Rights, 2005", on Risk Assessment and Management, which states: "*Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.*"[44]

Overall, the "Principle of Impact Assessment" is essential to guarantee the responsible, safe, and ethical use of HGE. It necessitates careful consideration of the advantages and disadvantages, as well as a dedication to constant observation and assessment. The "Principle of Impact Assessment" would compel a State to evaluate the risks associated with GET, including its potential effects on human health and human rights, before allowing its clinical implementation.

v. Social Inequality and Economic Division: The development of gene editing techniques such as *"CRISPR/Cas9"* has spurred significant debate throughout the world about the possibility of making *"designer babies"*. The socio-legal and ethical concerns with embryo gene editing for medical purposes necessitate prudence as well as planned and proactive research. One significant issue is the potential use of embryo germline editing for non-therapeutic research, which might result in the production of *"designer human babies"* with particular and desired qualities. Such actions could lead to a society that is unequally divided, with those who can afford to give their offspring designer qualities having an unfair edge over others who cannot.

The commercialization of HGET presents new issues, specifically around affordability and price. People might not hesitate to choose specific features for their unborn child, such as skin tone, eye colour, hair type, appearance, physical endurance, and other desirable traits if such technology is offered based on its price. This can aggravate current social injustices and spark a socio-economic confrontation.

While GET has the potential to provide tremendous benefits, many questions remain unsolved. For instance, the costs associated with GET, its accessibility for human benefit, the best way for ensuring responsible and ethical utilisation of the technology, and any unknown consequences of its use, all must be taken into account. Like any other emerging technologies, GET also has both advantages and disadvantages. Concerns that need to be carefully considered include those relating to the accessibility of these technologies to the general public at reasonable costs and expenses, challenges in marketing and commercialization,

[44] Universal Declaration on Bioethics and Human Rights, 2005, art. 20.

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economic interests affecting their therapeutic use, patenting, and anticipating unintended consequences.

The *"Universal Declaration of Human Rights"*[45] affirms the right to life, liberty, and security of person, as well as the right to be free from discrimination.[46] International laws and rules have been put in place to make sure that GET is utilised ethically, in compliance with human rights values, and for the good of humanity. Any use of GET must be done cautiously, subject to rigorous testing, and with proper consideration of ethical and legal issues. Despite the fact that technology has the potential to have major positive effects, it is imperative to address the moral, social, and legal issues it poses.[47]

V. CONCLUSION & RECOMMENDATIONS:

Human Gene Editing Technology significantly paves the way for a better future with the help of the prospective ability to cure rare genetic diseases and improve human health but brings along with it huge risks that demand a systematic and precautionary approach. Cautious research work in the area of HGE is the need of hour, followed by a detailed study of long-term future benefits and risks to the participants. While potentially utilising the prospects of science and technology, we must ensure that the "*Right to Health*" of every citizen must be maintained without any harm. Necessary safeguards, training, and rehabilitation of research personnel, with regard to psychological and societal issues while promoting the research must be assured. Adequate steps must be initiated to make people aware of the new technology and related issues, individual rights and their protection, and safeguard against all sorts of discrimination. India is a developing country and it is equal important for it to invest in technologies like HGE since we have been struggling with inherited and complex diseases that end up with very limited or no treatment. Mass involvement of the public through debate, discussion, seminars, conferences, awareness camps, etc. should be encouraged so as to promote knowledge against unwarranted fear related to this boon of technology. All round efforts together from all the stakeholders of the society, including academicians, lawyers, businessmen, government agencies, and civil society are required to improve the existing guidelines with regard to the socio-ethical norms. This would ensure appropriate implementation, promote a healthy society, help progress in

[45] Universal Declaration of Human Rights, 1948.

[46] Universal Declaration of Human Rights, 1948.

[47] Roli Mathur, "Ethical Considerations in Human Genome Editing-An Indian Perspective", 20 Asian Biotechnology and Development Review 47-58 (2018).

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the field of science and technology while acknowledging legal and ethical concerns, and protect and preserve the interests of both the present and future generations.

GET in order to be successful and acceptable to the public at large, demands community awareness and education. There is a dire need to consult with various sections of society to overcome issues of socio-economic or religious, cultural beliefs or concerns. Moreover, accountability on behalf of the stakeholders involved in GET and transparency in research is also required. Research findings of Gene Editing including both positive and negative sides must be brought into the public domain for further elaborate discussions.

HGET comes with plenty of benefits and risks that need to be explored. Thus, careful scrutiny is expected to ensure the benefits. Certain recommendations and suggestions for the safe use of HGET are:

1. **Improve Global Regulatory Frameworks:** The International community must collaborate to create stricter rules and standards for HGE, with a focus on preventing the improper use of this technology. The scientific community, International organisations, and various States can work together to accomplish this.

2. **Create Ethical Principles for the Commercialisation of Human Gene Editing:** There is a chance that GET will be applied in ways that are inconsistent with universally acceptable ethical standards as it becomes more commercially available. In order to solve this, ethical standards must be developed to control the commercialization of HGE, including the price and accessibility of the technology for the general public.

3. **Promote Transparency and Public Engagement:** Transparency and opportunity for public participation in decision-making processes are necessary to build trust and legitimacy in the regulation of HGE. This entails interacting with stakeholders, such as patients, health workers, advocacy organisations, and the general public, to make sure their viewpoints are taken into account.

4. **Strengthening the Informed Consent Procedure:** Ensuring that people are properly informed about the dangers and advantages of gene editing as well as its long-term effects, it requires strengthening the informed consent procedure for HGE. This includes letting people know about the possible social, economic, health, and ethical consequences of gene editing as well as the likelihood of unanticipated outcomes.

5. **Create a Global Database to keep track of Human Gene Editing Clinical Studies:** A single digital database for tracking clinical research and results is required to better understand the advantages and hazards of HGE. This will make it easier to spot possible problems and areas that require more study.

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6. **Promote Responsible Innovation:** Innovation is essential for improving the science of HGE, but it must be done so in a responsible manner. This necessitates an emphasis on the responsible development, implementation, and use of gene editing technologies to guarantee that they are utilised for the benefit of society as a whole.

7. **Provide means for Monitoring and Enforcing Regulations:** Adherence to the ethical and legal frameworks for HGE depends on effective processes for monitoring and enforcing regulations. This includes procedures for keeping an eye on research, documenting results, and holding people and organisations responsible for violations.

The regulation of Gene Therapy Trials (GTT) has been developed by numerous nations worldwide. Therefore, it is vital to create national policies and laws to inform researchers, medical professionals, and business leaders about the steps to be taken in order to do Human Gene Editing (HGE) in India. India currently needs clear norms, regulations, and a robust legal framework in the realm of Gene Editing. It is crucial to think carefully and explore its ethical applications in society. In order to formulate and elucidate ethical norms and regulations for the safe use of this technology, thorough intellectual deliberation and careful analysis of its pros and cons are indispensable.

India boasts excellent scientists and a comprehensive legal system. Due to the work of committed scientists, lawyers, and national and international institutions, there is a wealth of information accessible that can help build infrastructure in the Indian context by creating appropriate regulations in the disciplines of HGET. These are some suggestions specifically for India:

1. **Significance of a Precise Human Gene Editing Legislation:** The most urgent requirement of the hour for reaping the benefits of the genetic revolution is precise, unambiguous, complete scientific HGE legislation. The proposed legislation serves a variety of purposes. First of all, it would offer explicit recommendations on the standards to be followed by the research and medical organisations involved in genetic research. It will also clarify a number of legal and moral issues connected to HGET.

2. **Formation of the National Human Genetics Commission:** It is advisable to establish a National Human Genetics Commission to offer high-level technical and strategic guidance on current and developing concerns in human genetics, as well as to serve as a consultation mechanism for the creation of National Genetic Policies and guidelines in that field.

3. **Rules for Protecting Genetic Privacy:** Additionally, it is suggested that complete genetic legislation include guidelines to safeguard genetic privacy. It ought to include

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provisions for both the dissemination of genetic data and the preservation of genetic sample privacy. DNA testing involves three types of privacy invasion: bodily privacy when a sample is taken from a person's body; genetic privacy when the sample is used to predict a person's future health and other characteristics; and behavioural privacy when the information is used to track a person's whereabouts and activities. When weighing civil liberties against the broader interests of the community, privacy and respect for human dignity do not have to be sacrificed. The integrity and legality of genetic testing can be improved by the formulation of strong privacy laws. The community would feel more secure knowing that privacy protections are being made in the name of improved security and safety if the principles governing privacy had a statutory basis.

4. **More Effective Human Gene Editing Technology Use:** More effective process-specific and disease-specific guidelines, are to be formulated in order to guarantee that the use of HGET is restricted to acceptable reasons. Such recommendations would aid in preventing the improper use of HGET, particularly when it is inappropriate or might endanger the patient. Additionally, the rules would help to guarantee that HGET is only used for the intended purposes, under the proper level of supervision, and in accordance with ethical and legal standards.

5. **Misuse of Human Gene Editing Technology to be a Specific Crime and Establishing Civil Liability:** Misuse of HGET must be accepted as a specific crime for which provisions of imprisonment and fine are to be inserted in the Indian Legal System. Civil liability must be imposed if any medical institution/clinic or researcher does not follow the ethical principles prescribed by the various guidelines.

6. **Providing Technical Training for Court Officials:** There is no need to create science courts to address matters that arise from them because our judiciary already has systems in place to handle scientific issues. However, in order for court authorities to understand the scientific evidence, they must be given technical and scientific training.

7. **Expanding the Scope of Fundamental Rights:** Legislators and policymakers should take seriously the idea of expanding the notion of fundamental rights beyond those applicable only to State entities. The genetic revolution would put a lot of information in the hands of private companies, which will lead to a lot of human rights violations. In addition, genetic discrimination needs to be added to the list of illegal bases for discrimination in Article 15 and 16 of the Constitution of India. In the meanwhile, the Indian judiciary may view these situations as infringing on the extended part of Article 21 guaranteeing life and liberty.

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Ultimately, establishing the Legal and Ethical Framework for HGE would necessitate a comprehensive strategy involving collaboration across different sectors and stakeholders. Together, we can make sure that the Human Gene Editing Technology is applied ethically and for the good of society at large.

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