Human Gene Editing and Its Inherent Conundrums: Legal Perspectives

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Abstract

Gene Editing, as a work of human ingenuity and innovation, opens up a vast range of possibilities for human existence in the future. While Gene Editing, on the surface, opens up the possibility of human perfection, it also raises a slew of ethical, philosophical, economic, and legal difficulties. From the standpoint of India's commitment to ensuring an egalitarian society in which access to the fruits of science and technology is made available to both the rich and the poor, the prospect of Gene Editing raises deep and complex questions about the disparity in the capacity of the less resourceful to reap the benefits of this scientific advancement. The propriety of pushing such a disruptive technology - of men having the potential to fundamentally and dramatically alter nature's systems of creation and sustenance - is also a factor in Gene Editing. Gene Editing also brings up the classic "Frankenstein" question: are we unleashing a beast beyond our control? Is it possible to get a global consensus on Gene Editing's inherent limitations, if there are any? Because Gene Editing involves decrypting the fundamental building components of any human person, it raises the important question of whether such information should be made public, as well as the risks that come with it. Within its limited scope, this study makes a determined effort to address the aforementioned conundrums. It also attempts to provide a glimpse into the future that we are moving towards in terms of Human Gene Editing. While the scope of the various issues relating to Gene Editing is vast, the paper focuses primarily on the dimensions of Gene Editing's economic perspective in India, its ethics, law, and scientific progress, informed consent and counselling in the domain of Gene Editing, and the need for transparency and accountability in the domain of Gene Editing.

Keywords: *Human Gene Editing, CRISPR-Cas9, Law, Ethics, Governance, Regulation.*

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I. Introduction

The 'Gene Editing' Technology is a prodigy by itself. It has grasped a good amount of attention in a little span of time, specifically, since two women researchers, namely, "Emmanuelle Charpentier and Jennifer A. Doudna were awarded with the Nobel Prize in Chemistry, by the Royal Swedish Academy of Sciences, in 2020, for the development of a method for Gene Editing."[3] This indeed encouraged the significant role a promising technology of this kind may play in the advancement of human health. With the application of gene editing technologies involving the CRISPR-Cas9 and other comparable molecular scissors, scientists and researchers can make a breakthrough in healing a variety of severe diseases.[4] It's a sign of good things to come. This necessitates for a competent legal framework that will both improve and constrain the anticipated technical advancements. The ethical and moral considerations must be addressed right from the start, which will help the researchers and policymakers use the framework in the process of development and implementation of this new technology, hence, benefiting society to the best extent possible.

Various bioethicists and researchers from around the world have been debating the legal and ethical challenges that have arisen as a result of the usage of gene editing technologies in recent years.[5] In terms of India, it is right time to recognise these scientific and ethical concerns and establish a regulatory framework for the application of this unique technology. It is crucial to advance science and technology; yet, it is also critical to use the best research available in the greater interest of humanity without inflicting harm. Given the socio-economic difference, it is necessary to thoroughly assess the benefits and drawbacks of this technology. Actual facts, not false notions, must be adhered to in order to facilitate improved comprehension and expand opportunities. In order to launch prospective advances in human health, a new technology that is

[3] The Royal Swedish Academy of Sciences, "Press Release: The Nobel Prize in Chemistry 2020", *Nobel Prize Org.*, (7th October 2020), *available at:* https://www.nobelprize.org/prizes/chemistry/2020/press-release/ (last visited on Feb. 21, 2021).

[4] David Baltimore, Paul Berg P, *et. al.*, "A prudent path forward for genomic engineering and germline gene modification", *Science*, 36-38, 348 (6230) (2015).

[5] Arthur L Caplan, Brendan Parent, *et. al.,* "No time to waste - the ethical challenges created by CRISPR", EMBO Reports, 1421-1426, 16(11) (2015).

still in the development stage but has huge promise must be explored to broader boundaries.[6]

II. Indian Perspective of Human Gene Editing

A large proportion of the Indian population is afflicted by complex diseases and even hereditary monogenic ailments that have no treatment alternatives. These genetic abnormalities frequently result in life-long incapacity, putting a financial strain on society and putting a strain on India's healthcare system. "Haemophilia, thalassemia, sickle-cell anaemia, muscular dystrophies, retinitis pigmentosa, primary immunodeficiency (PID) in children, lysosomal storage disorders such as Pompe disease, Gaucher's disease, haemangioma, cystic fibrosis, and others are only a few examples of complex diseases. In India, 11,586 persons have been diagnosed with haemophilia A, with a frequency of roughly 50,000 patients. Similarly, there are approximately 100,000 thalassemia patients, 150,000 sickle cell patients, 500,000 (Duchenne Muscular Dystrophy) muscular dystrophy patients, and a greater incidence of 1 in 4000 retinal dystrophies."[7] Furthermore, unusual genetic illnesses must be addressed urgently. "The morbidity and mortality associated with uncommon genetic illnesses are unknown due to a lack of epidemiological data on their prevalence and burden. However, based on an International estimate of 6% to 8% of the population being affected by rare diseases, India's population of 72 to 96 million people is likely to be affected by rare diseases, which is a major source of concern for the health-care industry."[8] As a result, it's critical to develop new, safe, and focused treatments for all of these illnesses among Indian patients. Changing a person's genetic makeup is a difficult task, both scientifically and physiologically. It is possible to relieve patients' suffering provided correct scientific and ethical protocols are followed.

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[6] Richard Owen, Phil Macnaghten P, *et. al.,* "Responsible research and innovation: From science in society to science for society, with society", *Science and Public Policy*, 751-760, 39 (2012).

[7] 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", 5 (November, 2019), *available at:* https://main.icmr.nic.in/sites/default/files/guidelines/guidelines_GTP.pdf (last visited on August 25, 2021).

[8] *Id.*

III. The Scientific Progress of Gene Editing

Gene editing traces back to the late 1980s, however it came into limelight in the year 2012 when two women scientists, namely, Jennifer Doudna and Emmanuelle Charpentier established that the CRISPR technology could be utilised to edit genes. Gene Editing is a difficult task since it limits how far scientists can alter genomes.[9] Despite the potential hazards involved with the technology, practically any part of a genome, whether in plants, animals, or humans, might be altered precisely and reliably. Genetic engineering is not a new concept; scientists have long used various approaches to change genes.[10] However, gene editing differs in that it is simple, inexpensive, and precise, allowing genetic engineering on a previously unimagined scale. Such a technology can be utilised to produce and conduct various medical treatments and develop vaccines as well. Gene editing associates itself with various approaches but CRISPR-Cas9 has hit the spotlight.[11]

Gene Editing includes making changes to a specific target in a cell's DNA. This alteration can bear the consequence of introducing a modest deletion or even a precise sequence change. Gene editing can be applied through various modes, although "**Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR/Cas9)**"[12] is currently the most straightforward. In 2012, the CRISPR-Cas9 technology was first published.[13] CRISPR-Cas9 is a versatile method that may be employed without any prior knowledge of protein engineering. Because of the method's nature, many changes affect a cell at the

[9] Puping Liang, Yanwen Xu, *et. al.*, "CRISPR/Cas9-Mediated Gene Editing in Human Tripronuclear Zygotes", *Protein Cell,* 363-372*,* 6 (5) (May, 2015).

[10] David Cyranoski, "CRISPR Gene-Editing Tested in a Person for the First Time", *Nature,* 479, 539 (November, 2016)

[11] Bonny Lemma, "CRISPR Dreams, The Potential for Gene Editing", *Harvard International Review*, 6-7, Vol. 40, No. 1 (2019)

[12] Your Genome Organisation, "What is CRISPR-Cas9?", *available at :* https://www.yourgenome.org/facts/what-is-crispr-cas9#:~:text=The%20CRISPR%2DCas9%20system%20consists,then%20be%20added%20or%20removed (last visited on March 20, 2021).

[13] Martin Jinek, Krzysztof Chylinski, *et. al.,* "A programmable dual-RNA-guided DNA endonuclease in adaptive bacterial immunity", *SCIENCE*, 816-21, 337 (6096) (August, 17, 2012).

same time. CRISPR-Cas9, although its ease of use and inexpensive cost, is not without flaws.[14]

IV. Gene-Therapy Ethics: Somatic vs. Germline

The ability to create accurate modifications within the human genes, be it somatic or germline, leads to fundamental concerns about how far it may be used in a socially acceptable manner. As a result, we must comprehend the fact that germline gene editing alterations may be heritable, and questions such as whether gene editing techniques should be employed to prevent genetic disorders or not and whether genetic enhancement upon severe disorders must be addressed.[15] It's high time, one should distinct the features of Gene Editing techniques, in terms of what is acceptable and what is not.[16] It's unclear if germline gene editing will be a boon or a bane for humanity.[17] Modifications are not heritable and will not be passed down to future generations, in case of somatic cell gene editing as because they may require similar treatment. It has therapeutic promise and has the ability to remove disease, resulting in a higher quality of life.[18] However, due to the current level of our understanding, Gene Editing may create concerns that are yet unresolved, extreme caution is required. An International moratorium on clinical use of human germline editing was announced, preventing the creation of genetically modified children and providing time for debate on moral, ethical, scientific, societal, and legal issues, as well as the development of regulatory frameworks to govern the technology.[19] There has been a progressive start but highlighted with

[14] Fani Memi, Aglaia Ntokou, *et. al.,* "CRISPR/Cas9 Gene-Editing: Research Technologies, Clinical Applications and Ethical Considerations"*, Semin Perinatol,* 487-500, 42(8) (December, 2018)

[15] E Lanphier, Fyodor Urnov, *et. al.*, "Don't edit the human germ line", *Nature*, 519: 410-411 (March, 2015).

[16] J. Benjamin Hurlbut, Krishanu Saha, *et. al.*, "CRISPR Democracy: Gene Editing and the Need for Inclusive Deliberation", *Issues in Science and Technology*, FALL, 25-32 , Vol. 32, No. 1 (FALL 2015).

[17] K Krishan, T Kanchan, *et. al.,* "Germline Editing: Editors Cautionary"*, Clin. Ter.,* e58-e59*,* 169 (2) (2018).

[18] Otieno MO, "CRISPR-Cas9 Human Genome Editing: Challenges , Ethical Concerns ans Implications", *Journal of Clinical Research & Bioethics,* 6:6 (December 26, 2015).

[19] The National Academies of Sciences, Engineering, and Medicine, "On Human Gene Editing: International Summit Statement" (2015).

controversies, like- In China, delivery of twin babies with a gene modified for HIV, which received wide condemnation by the International community.[20] It was thought to be a scientific breakthrough, yet found to be unethical and morally reprehensible. The scientific community slammed it and openly rejected it, citing flaws in the investigators' safety assessments, ethics review, and informed consent, among other things.[21] This example demonstrates the significance of having a governance and monitored framework, as well as ensure that scientific research is conducted in a socio-culturally acceptable way, so as to support community values and practices. Further, here underlies a specific responsibility of removing fears and reluctancy associated with irreversible changes or inaccuracy in germline gene editing, off target mutations, probable implications upon future generations, interactivity with other genetic variations or misuse for prenatal testing, resulting to fetal manipulations which remain unregistered, creation of designer babies, eugenic practices or similar exploitations as such.[22]

V. Emerging Ethical Issues

In the realm of scientific study and development, ethics plays an important role. Integrating ethical principles and values would protect and promote high-quality research. An ethical review is significant because scientific technology and social norms have to be acknowledged by the researcher in order to conduct a research project ethically while assuring safety of the participants, which will, thus, protect rights, incorporate monitoring, and remain harmless.[23] The participants must have a complete overview of the situation and make their own

[20] Marilynn Marchione, "Chinese Researcher claims first Gene-Edited Babies", *AP NEWS* , Nov. 26, 2018, *available at:* https://apnews.com/article/ap-top-news-international-news-ca-state-wire-genetic-frontiers-health-4997bb7aa36c45449b488e19ac83e86d (last visited on January 26, 2021).

[21] Erika Kleiderman and Ubaka Ogbogu, "Realigning gene editing with clinical research ethics: What the "CRISPR Twins" debacle means for Chinese and international research ethics governance", *Account Res*., 257-264, 26(4) (May, 2019).

[22] The National Academies of Sciences, Engineering, and Medicine, "Committee on Human Gene Editing, Human Genome Editing: Science, Ethics, and Governance" (Washington, D.C.: The National Academies Press, 2017).

[23] Jennifer Kuzma and Lindsey Rawls, "Engineering the Wild: Gene Drives and Intergenerational Equity", *Jurimetrics*, 279-296, Vol. 56, No. 3 (2016), *available at:* https://www.jstor.org/stable/26322676 (last visited on November 19, 2021).

decisions. As a result, it is critical that Gene Editing research be thoroughly examined by an ethics committee that is competent, up to date, prompt, and independent in its assessment and decision-making processes.[24] An ethics committee's recommendations can help enhance the entire study and provide protection to the participants. Currently, this unique technology has potential therapeutic benefits in case of healing diseases but also accompanies with it, hazards. The ratio between the benefit and risks must be adjusted in a way which favours humanity.[25] Guaranteed advantages and minimized hazards, are two important aspects related to the safe use of Gene Editing technology which is in question right now. At this time, there are a number of ambiguous technological risks, many of which are unknown and unproven based on current knowledge. Protection of people must be ascertained through prevention of exploitation, proper counselling and mechanisms, with the use of this technology. It becomes vital while working with people of vulnerable nature, whether because of a disease, condition, age, or lack of comprehension. Moreover, they require greater safety also for their autonomy, as they may not be able to preserve their own rights. Any personally identifiable information must be appropriately protected and clinical records must be meticulously preserved with access to few authorised individuals only.[26] Gene Editing, involving any synergetic research that requires data sharing must also address concerns about personal clinical information of those involved in the project.[27]

VI. Social Inequality and Justice

There are a number of socio-economic concerns about the possible use of embryo Gene Editing for healthcare purposes, all of which require more investigation. There's a chance that embryo germline editing might be used in non-therapeutic research, may be to create designer kids with specific characteristics. Designer traits or specific qualities of certain eye colour, height,

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[24] Indian Council of Medical Research (ICMR), "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017", 22 (October, 2017), *available at:* https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last visited on August 25, 2021).

[25] *Id.*

[26] *Id.*

[27] *Id.*

hair, complexion or even physical endurance of kids might be inserted, if humans get an easy control over Gene Editing and more, if it becomes commercially available on the basis of affordability.[28] Thus, resulting in a socio-economic divide and societal inequity. There are still unanswered questions about the high costs of technology, when it should be used, how to ensure benefit sharing and access, and when it should not be utilised. In the lack of efficient communication, there can be significant societal issues and misunderstanding among the general population. It is necessary to explain the ramifications of giving solutions in agriculture, pest resistance, sustainable farming, and the treatment of life-threatening diseases such as cancer, muscular dystrophy, diabetes, thalassemia, and others. Community engagement and education could be crucial in making technology acceptable and dispelling any unfounded fears. There is a need to engage people and address concerns about socio-economic, religious, or other cultural views, as well as societal difficulties. In circumstances where the technology is valuable, access must also be guaranteed. With any new technology, issues such as appropriate steps to make these technologies available to the general public at an affordable cost, issues related to marketing and commercialization, economic interests restricting therapeutic use, IPR and patenting, and unknown implications for the future of our society can be expected. Furthermore, all engaged stakeholders must be held accountable, and research must be conducted in a transparent manner.[29] Both positive and negative research findings should be conveyed and publicised so that they can be shared with stakeholders for further discussion. As a result, Gene Editing technologies must be thoroughly scrutinised to ensure that the benefits are passed down to future generations.[30]

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[28] Jane Brophy, "Dream Babies, China Dreams", *ANU Press* (2020), *available at:* https://www.jstor.org/stable/j.ctv12sdxmk.18 (last visited on January 25, 2021).

[29] K Krishan, T Kanchan, *et. al.,* "Germline Editing: Editors Cautionary"*, Clin. Ter.,* e58-e59*,* 169 (2) (2018).

[30] Roli Mathur, "Ethical Considerations in Human Genome Editing–An Indian Perspective"*, Asian Biotechnology and Development Review,* 47-58, Vol. 20 No. 1&2 (2018).

VII. Principle of Transparency and Accountability

New technologies pose an inherent challenge due to inadequate understanding and long-term consequences.[31] It becomes necessary to establish the accountability in the event of an unforeseeable occurrence, as well as assess the possible consequences. Understanding and implementing appropriate use of Gene Editing technology, as well as having mechanisms to safeguard, offer medical treatment and compensate from harm caused while conducting research, is a sound ethical practise.[32] All Gene Editing techniques and processes should be carried out in accordance with established guidelines and ensure transparency and reliability, equally. Implementation must be preceded by procedures subjected to a rigorous scientific and ethical evaluation, as well as a peer review process to ensure the most up-to-date understanding. To the degree practicable, all the stakeholders underline a shared obligation to ensure participant's safety and well-being and connected risks are minimised.[33] The research findings, whether favourable or negative, must be published in journals as soon as possible and made publicly available data's such as the "**Clinical Trial Registry-India (CTRI)**."[34] It is necessary to make efforts to communicate results and facilitate their translation for the benefit of others.[35]

VIII. Informed Consent and Scope for Counselling

Adequately informed and understood consent is a prerequisite for conducting any type of experiment, and it must improve voluntary decision-making without the appearance of coercion. This is the most critical factor for any type of biomedical study, but it is especially related to new technologies.[36] The information should be delivered and disseminated in a simple and

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[31] Sara Reardon, "NIH reiterates ban on editing human embryo DNA", *Nature, Breaking News* (29th April, 2015), *available at:* http://www.nature.com/news/nih-reiterates-ban-on-editina-human-embrvodna-1.17452 (last visited on November 15, 2021).

[32] Marcy Darnovsky, Nathaniel Comfort, *et. al.,* "CRISPR Regulation", *Issues in Science and Technology,* 5-12, Vol. 35, No. 4 (2019).

[33] *Supra* note 24, at 4.

[34] *Supra* note 24, at 18.

[35] *Supra* note 24, at 4.

[36] R. Isasi, E. Kleiderman, *et. al.,* "Editing policy to fit the Genome?", *Science, New Series,* 337-339, Vol. 351, No. 6271 (2016), *available at:* https://www.jstor.org/stable/24741334 (last visited on January 19, 2021).

comprehendible language. Genetics terminology is often difficult to comprehend and contains technicalities which could be misunderstood if left without proper explanations. Genetic testing must be followed by non-directed pre-post counselling to explore the options, limitations, and likely consequences and to facilitate understanding and voluntary consent which has to be provided without any undue influence or coercion.[37] There should be adequate chances of denial or acceptance to participation and even in case of participation, you should be able to withdraw at your own stance. It is often critical to disseminate all details about potential adverse effects, many of which may be unknown based on current knowledge. The procedure should not be rushed, allowing enough of time and opportunity to talk about it in private. The research has to be organised in a way culturally acceptable and language easily understood; and preferably by those who can commit gently and provide appropriate answer to the doubts, may be by a genetic counsellor or a lead investigator. Informed consent is a process, which is beyond a piece of paper and the interaction must undertake throughout the study.[38] Research experiments must involve strict compliance and cautious approach while receiving consent.[39]

IX. Bridge between Public Trust and Science and Technology

The scientists and society, both are critical, without which giving effect to positive change would be impossible. The Gene Editing benefits can be gained, when ethical issues get addressed up front, and communication gets enhanced and carried out in a way that is easily understood by the general public. To effectively communicate science, you'll need skills, enthusiasm, and initiative to unravel its complexity. Researchers, doctors, bioethicists, ethical committees, legal experts, social scientists, research institutions, and policymakers must examine all the concerns surrounding Gene Editing in depth.[40] To progress in the use of technology for the greater good, efforts must be made to comprehend, connect, properly disseminate and create a public

[37] *Supra* note 24, at 113.

[38] Roli Mathur, "Gene Editing - Ethical Pathways to Connect Science & Society*", Asian Biotechnology and Development Review*, 43, Vol. 23 No. 1 (2021).

[39] *Supra* note 24, at 114.

[40] Brendan P. Foht, "Gene Editing: New Technology, Old Moral Questions", *The New Atlantis*, 3-15, No. 48 (Winter 2016).

conversation in which all the advantages and drawbacks may be explored.[41] Fair, honest, and open talks are required, as well as the use of various advocacy venues. Understanding local sentiments, practises, or religious beliefs which may impact public decision is critical at this time. An open discourse will aid in improving knowledge, dispelling doubts, and ultimately fostering faith in technology. Typically, researchers and scientists develop technology in laboratories and present their findings but these findings relate to a tiny audience but not the general public.[42] It is necessary to make efforts to engage with the general public by translating these discoveries into a simple form or style that is relevant to bigger audience. All the parties must work jointly to identify methods to engage the public, which has to start from the beginning of the project. They must discuss the plan's specifics, predicted outcomes, potential constraints, methods, and result into benefits. Furthermore, a conversation on how to ensure trust, eliminate unneeded stress and assure positivity must be held. Another factor to consider is that public trust does not develop overnight, and that engagement is a process that is determined by how frequently and successfully scientists communicate and respond to the public in an understandable language. Open public debates at the regional level, broader stakeholder meetings, generating advocacy, connecting with social media, such as newspaper articles or television channels, are some of the techniques that have proven to be effective. Public Trust can be assured by the community, if significant efforts are initiated in a culturally sensitive way while conducting research.[43]

X. Technology Access and Distributive Justice

Another significant responsibility must be to ensure measures that could make Gene Editing technology available to those who require it. At this time, no one knows if this will be an extremely expensive technology that will only be available to a select few who will benefit.[44] Is it really ethical if the technology is only available to a few privileged people while the rest remain mainly uninformed of it and have limited resources to acquire it? It's critical to debate

[41] *Supra* note 24, at 11.
[42] *Supra* note 38, at 44-45.
[43] *Supra* note 24, at 141.
[44] Rama Devi Mittal., "Gene Editing in Clinical Practice: Where are We?"*, Indian J. Clin. Biochem.,* 19–25, 34(1) (2019).

which applications of technology are permissible and for whom. How will folks be able to get their hands on these? What are the options for ensuring equal access? There is the task of making technology acceptable and dispelling unfounded fears, and also ensuring that technology is equitably and beneficially enjoyed by all. Proper investments are required to accelerate the technological development so that it could be easily accessible and inexpensive to people who require them. In India, the government agencies as well as other sponsors are expected to provide significant funding for the progressive research while also educating, training, benefiting, and developing advocacy tactics to improve comprehension and, ultimately, acceptability.[45] It is also critical to ensure that India advances and is able to meet the country's needs after the fruits of research have blossomed. There is a commercialization and profiteering component to the technology because most genetic testing is extremely expensive and only available at a few specialised institutes.[46] Despite the fact that the technology is not expensive in and of itself, the commercial potential for treating a range of significant genetic illnesses, malignancies, and other polygenic diseases has piqued the interest of private players. As science progresses toward providing individualised medication to humans, the technology risks being limited to those who can pay it. To protect ethics and initiate equity and access to breakthrough technologies to sustain mankind, all of these problems must be discussed on a larger scale.[47]

XI. Capacity Building and Collaborative Research

Only a few institutions have the facilities and mandate to conduct extensive Gene Editing research.[48] Unless further chances arise, the influential people will reap the benefits from the technology and qualified labour will remain scarce to work with novel research approaches. Institutions must provide a supportive enhancement to promote breakthrough research, as well as create an environment for inventive work, scientific exploration independence and infrastructure solving the purpose. Institutional assistance with regards to policy

[45] *Supra* note 24, at 8.
[46] *Supra* note 38, at 46.
[47] Andrew W. Torrance, "CRISPR Becomes Clearer", *The Hastings Center Report*, 5-6, Vol. 47, No. 5 (September-October 2017), *available at:* https://www.jstor.org/stable/26628303 (last visited on January 19, 2021).
[48] *Supra* note 38, at 47.

making and leadership is critical in encouraging people to engage in research and development. Investments in lab work may be required to initiate assistance, training, collaborations, resource sharing, and exchanges of ideas. Specific objectives, cooperation, roles and duties, data sharing, publications, patents etc. must be ascertained when there is a collaborative research.[49] The government must develop the research on Gene Editing techniques and build connections for bench to bedside including medical personnel.[50] All parties must now work together to establish communication, develop collaboration, and build trust.[51] Because this is a new field, more scientists and medical professionals may be required to collaborate in order to explore ways to improve human health while adhering to proper regulatory and ethical considerations.[52]

XII. The Need for an Indian Legal Framework

The governance of Gene Editing involves a number of parties. Various institutions, committees, sponsors, regulators, government agencies and everyone else associated with conduct, review and monitor research are all affected. The policy framework must be designed in that way which promotes high-quality research, assists in translating advantages to the general public, and regulates, monitors, and protects the general public's interests. There is a need to assess the frameworks which regulate technology in order to support public-interest. Despite lack of clear rules, there are principles and regulations in place that would make it easier to regulate Gene Editing research and uses.[53]

Speaking of India, *"**The Rules for the Manufacture/Use/Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms***

[49] The National Academies of Sciences, Engineering, and Medicine, *Human Genome Editing: Science, Ethics, and Governance* (USA, 2017).
[50] *Supra* note 24, at 124-125.
[51] Steven Pinker, "The moral imperative for bioethics", *The Boston Globe*, *available at:* https://www.bostonalobe.com/opinion/2015/07/31/the-moral-imperative-for-bioethics/JmEkovzlTAu9oQV76JrK9N/storv.html (August l, 2015) (last visited on November 15, 2021).
[52] *Supra* note 24, at 21.
[53] Murali Krishna Chimata and Gyanesh Bharti, "Regulation of Genome Editing Technologies in India"*, Transgenic Research,* 175–181, 28 (2019).

or Cells, 1989"[54] (known as the Rules, 1989) govern the Gene Editing technology. "**The Ministry of Environment, Forest and Climate Change (MoEFCC)**" enumerated these Rules in order to provide for a legislation with holistic framework to protect and preserve the environment under "***T*he Environment (Protection) Act, 1986 (the EPA, 1986)**."[55] Consecutively, various regulatory authorities, time and again, have set out guidelines and norms to address all such possible challenges which are imposed by modern Biotechnology. The Rules, 1989 provide for the competent authorities, their composition, powers and functions.[56] Accordingly, there are six competent authorities at present:

Table 1: Competent Authorities under "The Rules for the Manufacture/Use/Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989"[57]:

Name of the Authorities	**Role of the Authorities**
The Recombinant DNA Advisory Committee (RDAC)	Advisory
Institutional Biosafety Committee (IBSC)	
Review Committee on Genetic Manipulation (RCGM)	Regulatory/ Approval

[54] Ministry of Environment and Forests, *"The Rules for the Manufacture/Use/Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989*", (December 5, 1989), *available at:* http://www.indiaenvironmentportal.org.in/content/453231/rules-for-the-manufacture-use-import-export-and-storage-of-hazardous-micro-organisms-genetically-engineered-organisms-or-cells/ (last visited on August 26, 2021).

[55] Murali Krishna Chimata and Gyanesh Bharti, "Regulation of Genome Editing Technologies in India", 175-181, 28 *Transgenic Research* (2019), *available at:* https://doi.org/10.1007/s11248-019-00148-z (last visited on August 24, 2021).

[56] Vibha Ahuja, "Regulation of Emerging Gene Technologies in India", *BMC Proceedings*, 5-11 (2018).

[57] Ministry of Environment and Forests, *"The Rules for the Manufacture/Use/Import/Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989*", 2-5, (December 5, 1989), *available at:* http://www.indiaenvironmentportal.org.in/content/453231/rules-for-the-manufacture-use-import-export-and-storage-of-hazardous-micro-organisms-genetically-engineered-organisms-or-cells/ (last visited on August 26, 2021).

Genetic Engineering Approval Committee (GEAC)
State Biotechnology Coordination Committee (SBCC)
District Level Committee (DLC)
Monitoring

The use of Biomedicine in India is primarily administered by the "***Indian Council of Medical Research (ICMR), Department of Biotechnology (DBT) and Central Drug Standards Control Organization (CDSCO)***" Guidelines and Regulations. The DBT has been empowered under Section 6[58], Section 8[59] & Section 25[60] the EPA, 1986, adhering to which, it has ascertained to upgrade the existing guidelines namely: "*Recombinant DNA Safety Guidelines, 1990"*[61] and "*Revised Guidelines for Safety in Biotechnology, 1994"*[62] in the areas of bio-safety. National and International consultations have been acknowledged by the DBT in the process of notifying new guidelines titled: "***Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017***.*"*[63] These new guidelines are in replacement against the earlier ones. Wide scope of research, laboratory use, import/export, storage and handling, manufacture, disposal and emergency procedure and facility certification, all have been included in these guidelines.[64]

[58] "Rules to Regulate Environmental Pollution", the Environment (Protection) Act, 1986 (Act 29 of 1986), s. 6.

[59] "Person handling Hazardous Substances to comply with Procedural Safeguards", the Environment (Protection) Act, 1986 (Act 29 of 1986), s. 8.

[60] "Power to make Rules", the Environment (Protection) Act, 1986 (Act 29 of 1986), s. 25.

[61] Department of Biotechnology (DBT), "Recombinant DNA Safety Guidelines, 1990", (January, 1990) *available at:* https://biosafety.icar.gov.in/recombinant-dna-safety-guidelines-1990-2/ (last visited on September 15, 2021).

[62] Department of Biotechnology (DBT), "Revised Guidelines for Safety in Biotechnology, 1994", (May, 1994)*, available at:* http://biochem.du.ac.in/web/uploads/30%20Guidelines%20for%20Safety%20in%20Biotechnology.pdf (last visited on September 15, 2021).

[63] 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, 2021).

[64] Department of Biotechnology, Ministry of Science & Technology, Govt. Of India, "Office Memorandum: Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017", 1 (April 1, 2018), *available at:*

The Rules 1989 impose a duty upon the "***Institutional Biosafety Committees (IBSC's)***" and host institutions involving research, development and handling of Genetically Engineered Organism, to comply with the rules, failing which, it shall attract penal provisions under Sections 15[65], Section 16[66] & Section 17[67] of the EPA, 1986.[68]

The Indian Council of Medical Research's (ICMR's) "***National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017"***[69], ***"National Guidelines for Stem Cell Research, 2017"***[70], and ***"National Ethical Guidelines for Biomedical Research Involving Children"***[71] has acknowledged the ethical aspects of Gene Editing technology. All clinical trials initiated to develop products must follow "***The Drugs and***

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https://ibkp.dbtindia.gov.in/DBT_Content_Test/CMS/Guidelines/20181115134719867_Regulations-Guidelines-for-Reocminant-DNA-Research-and-Biocontainment-2017.pdf (last visited on August 26, 2021).

[65] "Penalty for contravention of the provisions of the Act and the rules, orders and directions", the Environment (Protection) Act, 1986 (Act 29 of 1986), s. 15.

[66] "Offences by Companies", the Environment (Protection) Act, 1986 (Act 29 of 1986), s. 16.

[67] "Offences by Government Departments", the Environment (Protection) Act, 1986 (Act 29 of 1986), s. 17.

[68] Department of Biotechnology, Ministry of Science & Technology, Govt. Of India, "Office Memorandum: Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017", 1 (April 1, 2018), *available at:* https://ibkp.dbtindia.gov.in/DBT_Content_Test/CMS/Guidelines/20181115134719867_Regulations-Guidelines-for-Reocminant-DNA-Research-and-Biocontainment-2017.pdf (last visited on August 26, 2021).

[69] Indian Council of Medical Research (ICMR), "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017", (October, 2017), *available at:* https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last visited on August 25, 2021).

[70] 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, 2021).

[71] 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, 2021).

Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945"[72] and ***"The New Drugs and Clinical Trials Rules, 2019"***[73]; which have provisions to regulate the new technology by CDSCO and also administer the conduct of clinical trials of new technology upon humans. The ICMR, CDSCO & DBT have jointly brought up a new ***"National Guidelines for Gene Therapy Product Development and Clinical Trials (2019)"***[74] as well, which provides description of requirement for the research and clinical trials.[75] The guidelines also provide a flow chart that explains the step-by-step procedures to be followed, including review by the CDSCO committee on gene/genetic alteration and oversight by the various committee such as: "Institutional Biosafety Committee, Ethics Committee, Review Committee on Genetic Manipulation, Gene Therapy Advisory and Evaluation Committee."[76] In India, in germline or *in utero* gene editing are currently forbidden, whereas somatic cell gene editing is permitted as part of a clinical trial study.[77] Before being filed to the CDSCO to be carried out as a clinical trial using a pre-clinical and clinical research model, the applications will need to be approved by multiple committees. Existing legal frameworks can be further modified and reinforced to assist Gene Editing technology and application. Within the regulatory system, there is a need to build expertise and capacity to tackle Human Gene Editing related concerns and guide against potential misuse of the technology. The government must make the necessary arrangements immediately to fund quality research studies through various grants, as well as ensure high-standard

[72] 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, 2021).

[73] 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, 2021).

[74] 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, 2021).

[75] *Id.*

[76] *Id.*

[77] *Id.*

outputs; and also implement socially acceptable, ethical, legal and regulatory framework for monitoring this new technology.[78]

XIII. Conclusion

Human Gene Editing technology appears to be too valuable for humanity to pass up, but it also has unintended consequences that should not be overlooked. With medicinal interventions especially suited to certain problems, it is a rapid, affordable, and remarkably precise technique to eradicate hereditary abnormalities. Not surprise, these are exciting times for research, and they hold out hope for patients suffering from terminal diseases. The first step in pursuing Gene Editing is to bridge the gap between research and society with a framework that is governed by ethical values. It is critical to raise public awareness about various elements of Gene Editing, as well as among other stakeholders such as researchers, clinicians, doctors, regulators and policymakers. Because this is a new area, knowledge and comprehension among the medical community will be limited, and efforts will be required to improve this and stimulate study. This is a constantly changing topic, and we must learn as the research advances and new global experiences emerge to inform the development of standards and regulatory frameworks. Ensuing state-of-the-art quality research in India can lead to the development of safe, economically accessible, and trust-worthy technology, making it affordable to the general public. To serve social interests, techniques must be humane, and efforts must be made to stay up with technological advancements in order to fully utilise them through sufficient involvement and communication. Before commercial implementation of Gene Editing technology, more extensive studies upon the socio-ethical and technical elements are required.[79] Scientists can make an experiment work in a lab because the setting is so regulated and ordered, but in real world it might fail. In cutting-edge science and technology, this is especially true. Off-target effects of Gene Editing technology must be controlled by some means. Policymakers and bio-security specialists are grappling to spot out and assess the troubles and advantage these new technologies associate with; because policy responses would be inadequate and less productive without proper assessment. To summarise, National regulation

[78] *Supra* note 38, at 47-48.

[79] Kathleen M. Vogel & Sonia Ben Ouagrham-Gormley, "Anticipating Emerging Biotechnology Threats: A case study of CRISPR", *Cambridge University Press; Politics and the Life Sciences*, 203-219, Vol. 37, No. 2 (Fall 2018), *available at:* https://www.jstor.org/stable/10.2307/26677575 (last visited on December 20, 2021).

of Human Gene Editing technologies (like CRISPR-Cas9) applications and commercialization is the best strategy to regulate the technology's societal implications in order to maximise public health benefits while minimising the potential of techno-racism or market-based eugenics. Human Gene Editing Technology may be impossible to halt,[80] but with enough foresight, countries may ensure that its use is focused on actual public health issues rather than what huge firms can pitch as problems that need to be solved with their products.

[80] James Kozubek, "Crispr-Cas9 is Impossible to Stop", *Georgetown Journal of International Affairs*, 112-119, Vol. 18, No. 2 (2017).