



Designer Babies: A Review

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Received: 23 November 2025

Revised: 05 December 2025

Accepted: 23 December 2025

ABSTRACT

Recent breakthroughs in the fields of Assisted Reproductive Technology, or ART, coupled with the advancement of Human Genetic Engineering, have dramatically transformed the realm of reproductive medicine in the present day, opening up immense possibilities in the medical treatment of infertile couples, as well as in the prevention of inherited disorders. These technologies, including In Vitro Fertilization, Preimplantation Genetic Testing, or PGT, and recent discoveries in genome editing, have made possible the selective implantation of embryos on the basis of their own unique genetic qualities, thus giving birth to the term “Designer Babies.” Although these technologies hold immense potential in ensuring better reproduction, as well as a reduction in the occurrence of inherited disorders, yet at the same time, raise numerous complex social, moral, legal, and ethical issues. The recent emergence in available Direct-to-Consumer Genomic Services has further fueled public debates over these issues, especially in terms of increased opportunities for couples to make their own informed, discretionary choices with respect to the inculcated qualities in their soon-to-be born babies, which at times go analytically beyond medical requirements to mere, unaltered, or discretionary wishes. Through this critical forum, this article aims to present an in-depth, analytic study on the “Ethical”.

Keywords: Designer babies, CRISPR-Cas9 technology, legal status

INTRODUCTION

A designer baby can be defined as the embryo or foetus whose genetic structure has been selected for reasons such as the absence of a certain gene, as well as the absence of genes responsible for various kinds of diseases to acquire desired characteristics (1). Genetically modified embryos can pass along their altered genetic properties to their offspring, leading to issues. The concept of creating a “perfect child” has become a possibility due to recent advances in reproductive medicine (2). Designer babies refer to children whose genetic makeup is deliberately modified through the integration of genetic engineering and in-vitro-fertilization (IVF). In recent years the idea has gained remarkable attention particularly among affluent societies and western countries. Building on the success of genetic modifications in animals scientists are now exploring similar applications in humans to achieve biological enhancement. The rapid advancement of biotechnology combined with intense competition for survival and innate human aspiration for superiority has fueled research in this area. The ultimate goal is to produce genetically engineered offspring who are not only free from hereditary diseases but also endowed with desirable physical, cognitive or behavioral traits there by representing a new frontier in human evolution (3).

REASONS BEHIND URGE TO CREATE DESIGNER BABIES

At present most designer babies are conceived with the primary objective of preventing the transmission of genetic disorders by selecting embryos that are free from disease-causing mutations. This approach can help avoid serious conditions such as cystic fibrosis and thalassemia. However in situations where all embryos inherit defective genes from carrier parents direct genetic modification becomes necessary. With the advent of advanced gene-editing technologies particularly tools like CRISPR-Cas9, Scientists now have the ability to alter the human genome with remarkable accuracy. These breakthroughs have brought the concept of designer babies closer to reality, not only as a means of eliminating hereditary diseases but also as a gateway to broader possibilities in human genetic enhancement (4).



HISTORY OF CREATING A DESIGNER BABY

This concept of designing a baby was arrived in middle of 19th century, first method was sperm donation in 1950s by the Dr. Raymond B. Bunge (US) and later many techniques were developed. The sequences of events were listed in the below Table 1.

Table 1: History and development of designer babies technologies (5)

Method/ technique	Year	Scientists/ Institutes	Role in designer babies
Sperm donation	1950-1960s	Dr. Raymond B. Bunge (US), Early sperm banks pioneers	Early sperm banks pioneers. Supplies sperm for fertilization when the intended father cannot produce viable sperm, facilitating genetic selection.
Cryopreservation	1950-1960s	Christopher Polge, A.S. Parkers, Dr. Jerome K. Sherman (US)	Allows the preservation of eggs, sperm, and embryos for future use, facilitating genetic selection and timing of implantation.
Invitro fertilization	1978	Dr. Robert Edwards & Dr. Patrick stepstone (UK)	Enables fertilization outside the body, facilitating the creation of embryos for genetic screening or modification.
Egg donation	1983	Dr. Subhash Mukherji (India), Dr. Robert Edwards (UK)	Provides healthy eggs for IVF when the intended mother cannot produce viable eggs, enabling genetic selection
Surrogacy	1980s	Historical practices date back to ancient civilization; modern legal frameworks developed in the 1980s	Individuals or couples who cannot carry a pregnancy to have a child, often involving IVF with genetic screening or modification.
Pre-implantation genetic diagnosis	1990	Dr. Alan Handyside (UK)	Allows genetic testing of embryos before implantation to select those without genetic disorders or with desired traits.
Mitochondria replacement therapy	1996-2019(initial procedures);2015(UK legal approval)	Dr. Jacques Cohen (US), UK parliament (2015 legislation)	Prevents the transmission of mitochondrial diseases by replacing defective mitochondria in eggs or embryos.
CRISPR-cas9 gene editing	2012(discovery);2015 (first human embryo editing)	Dr. Jennifer Doudna & Dr. Emmanuelle charpentier (US/France); Dr. shoukhrat mitalipov (US)	Enables precise editing of genes within embryos to correct genetic disorders or enhance traits.



TECHNIQUES FOR CREATION OF DESIGNER BABIES

The first technique used for designing a baby was pre-implantation genetic diagnosis. However, many other techniques were developed for creating a designer baby yet this pre-implantation genetic diagnosis was mostly preferred. The other techniques used in developing designer babies were enlisted below:

1. Assisted Reproductive Technologies (ART)
 - a] In-vitro fertilization (IVF)
 - b] Pre-implantation genetic diagnosis (PGD)
 - c] Surrogacy
 - d] Cryopreservation (Fertility preservation)
 - e] Egg donation and sperm donation
2. Mitochondria DNA Replacement Therapy
3. Cluster Regularly Interspaced Short Palindromic Repeats (CRISPR)

1. Assisted Reproductive Technologies (ART)

Assisted Reproductive Technologies (ART) are biomedical techniques in which pregnancy is induced through artificial or rather partially artificial procedures (6). ART entails the removal of an egg from a woman's ovaries, followed by fertilization in a lab (7). ART has also been utilized in the USA since 1981 and has resulted in the birth of over five million children world-wide (8). It is primarily utilized to assist an infertile couple in conceiving a child. Since there have been fast developments in the area, ART procedures are increasingly getting accepted in the medical field. They may be used in the selection and customization of embryos in the future.

a] In-vitro fertilization (IVF)

In-vitro Fertilization (IVF) is the first step that enables the observation, testing, and even altering of embryos before pregnancy. IVF is a fertility procedure wherein the egg is fertilized with the sperm outside the human body, in the laboratory (9). The procedure begins with the induction of ovulation with fertility medications, thereby letting several eggs develop simultaneously, instead of just one (10). After the injections of hormones for 10-14 days, the egg is retrieved with the help of a small surgery called follicular aspiration, with the aid of a thin needle guided with the ultrasound machine. The retrieved egg is then transferred to the lab for fertilization (11). In the case of normal sperms, the fertilization part requires merely the mixture of the egg and the sperms in the petri dish (12). In the case of poor sperms, ICSI (Intra Cytoplasmic Sperm Injection) technique is used, wherein a single sperm cell is injected inside the egg. The fertilized part of the egg is observed after 16-18 hours, and the resulting embryos are left for 2-3 days for growth. Finally, the healthiest embryos are implanted inside the woman's womb in the hope of a successful pregnancy (13). The process of IVF can be clearly mentioned in figure 1.

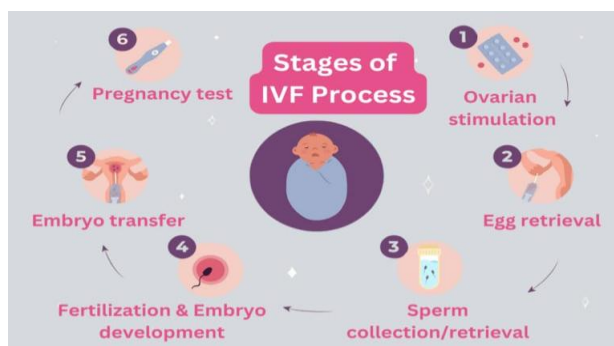


Figure 1: The IVF treatment process (14)

b) Pre-implantation genetic diagnosis (PGD)

Pre implantation genetic diagnosis refers to the process by which genetic disorders in embryos can be detected before pregnancy using IVF (in vitro fertilization). The common reason why PGD is applied is when one or both parents carry a genetic disorder (15). PGD was first applied on rabbit embryos in 1968, and in 1989, the first unaffected child was born from this process. After the process of IVF, the embryos undergo development to about eight cells within a couple of days. One of these cells is then analyzed using techniques such as polymerase chain reaction or fluorescence in situ hybridization (16). Cells that may have genetic disorders are not implanted into the uterus but rather disposed of (17). PGD helps prevent genetic diseases in children, but the chances of pregnancy remain low because many embryos may be abnormal, or the testing procedure may damage them (18). This process can easily explain in figure 2.

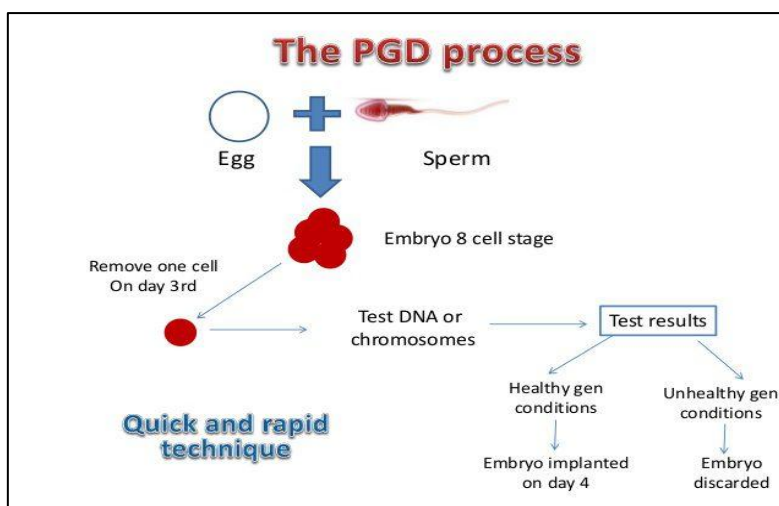


Figure 2: Preimplantation genetic diagnosis process (19)

c) Surrogacy

Surrogacy refers to a woman who carries a pregnancy and delivers the child on behalf of another individual or couple using their embryos or carrying their child conceived using their own eggs, which is also called traditional surrogacy if performed with the eggs of the surrogate, which are fertilized by the sperm, thereby making the surrogate mother, in contrast to gestational surrogacy in which the surrogate carries the IVF-generated embryo formed using the eggs and the sperm of the intending parents or donors, so in this, the surrogate has no link with the child at all. Laws on surrogacy differ from country to country, or rather, in different regions (20). This has been explained in figure 3.

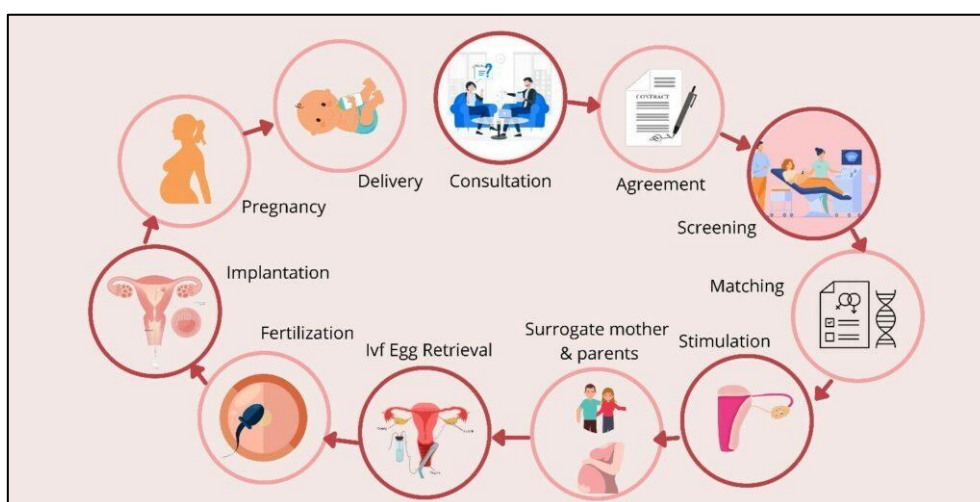


Figure 3: Surrogacy process (21)



d] Cryopreservation (Fertility preservation)

Cryopreservation is the freezing of eggs, sperm, or embryos for later use. It can be used in fertility preservation, such as in cancer patients, to preserve embryos that are in excess in assisted conception programs, or to put off childbearing. The use of vitrification rather than cryopreservation has enhanced success rates in IVF, which vary according to the eggs or sperm (22). For the reference, please look at the figure 4 below.



Figure 4: Cryopreservation process (23)

e] Egg donation and sperm donation

Egg and sperm donation ensures that those who cannot produce healthy eggs and/or sperm can also have babies. The eggs and/or sperm are donated by another person and are used in the different procedures of assisted reproduction, such as IVF and intrauterine insemination, to conceive. This genetic technology is used for those who cannot produce healthy eggs and/or sperm. This includes women who suffer from premature ovarian failure and poor egg quality, as well as men who do not have healthy sperm. Common among older women, same-sex couples, and single parents. Donations of eggs and sperm are important in the process of creating designer babies, particularly where genetic selection or the prevention of genetically inherited diseases is a consideration. Prospective donors are screened for medical and genetic disorders. Legal and moral issues in donor anonymity and parentage differ from one country to another (24). Benefits of traditional ART techniques include their proven track record, having decades of experience and success. Their personalization can be done as per the cause of infertility. Their widespread availability, which comes as most fertility centers in the world. The reference picture was given in figure 5.

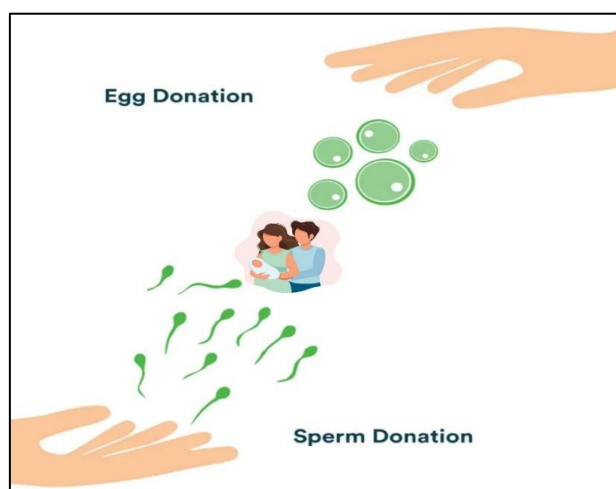


Figure 5: Egg and sperm donation in creation of a designed baby(25)



2. Mitochondria DNA Replacement Therapy

Mitochondrial Replacement Therapy (MRT) also known as mitochondrial donation. This is because the technique has been designed to help prevent the passing on of mitochondrial DNA disorders from mother to child (26). This is done by removing defective mitochondria present in the egg/embryo and replacing them with healthy mitochondria donated by another person, thereby ensuring that the child is not affected by mitochondrial diseases. This implies that through MRT, children can be produced using the genetic materials from three people: the mother, the father, and the mitochondrial donor; often called “three parent babies” (27). Ethical concerns associated with biotechnology include the issue of genetic modifications. This is especially the case when one considers the impacts that such can result on future populations. In particular, the technique is helpful for women affected by mitochondrial disorders wishing to deliver genetically related children. This procedure is illustrated by figure 6.

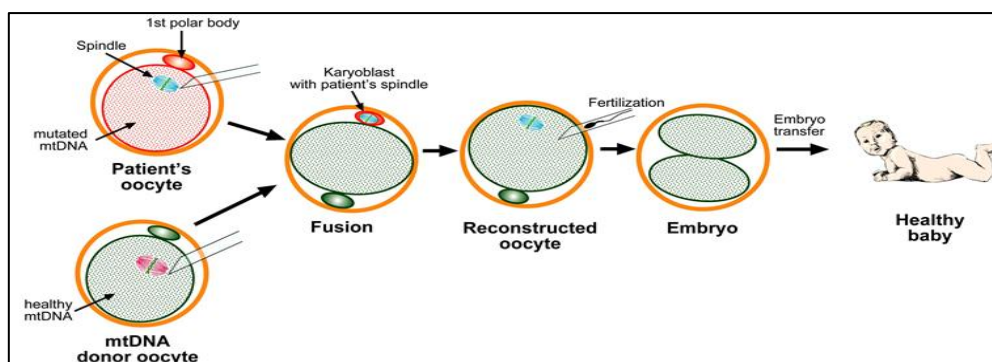


Figure 6: Mitochondria replacement therapy (28)

3. Cluster Regularly Interspaced Short Palindromic Repeats (CRISPR)

Biology is now at the dawn of a new era because of the CRISPR-Cas9, which is a powerful tool for gene editing. It has enabled scientists to edit genes with accuracy, providing hope for treatment of various genetic disorders. However, its use raises ethical concerns about how far genetic editing should go. Many fear it could be misused for human enhancement or creating so called Designer Babies. Therefore, it is important to set clear moral limits to ensure CRISPR-Cas9 is used responsibly. Genetic editing tools, like gene editing, are changing ART to help not only in fertility but also in the prevention of genetic illnesses. Gene editing in ART can reduce the risk of passing on genetic disorders from parents to offspring, assist in selecting healthier embryos, and improve the success rate of conception. It does so by meticulously altering particular genes in embryos, eggs, or sperm. A primary agent employed in this process is termed the CRISPR-Cas9 system (29). The CRISPR-Cas9 system facilitates careful manipulation of the genome by identifying particular DNA sequences wherein genes are to be inserted, removed, or modified. This technology is of tremendous significance in dealing with genetically inherited illnesses in embryos generated via IVF (30). Reference pic is provided in figure 7.



Figure 7: CRISPR method involved gene editing technique (31)



APPLICATIONS OF GENE EDITING IN ART

Gene editing is assisted reproductive technology (ART) can correct mutations in embryos and offers several important applications. It can prevent hereditary diseases such as cystic fibrosis, sickle cell anemia, and Huntington's disease, and helps stop these conditions from being passed on to future generations. Gene editing can also improve embryo selection by allowing screening and editing to choose the best-quality embryos, thereby increasing the chances of successful implantation and development. In some cases, it may help address infertility and can fix genetic problems such as chromosomal abnormalities and mutations affecting gamete function.

The pros and cons of designing a baby are given in Table 2.

Table 2: Pros and cons of designing a baby (32,33)

Pros	cons
Parents can select pleasing traits.	It's unethical.
Obviously, the gender of the child is selected	The technology is not as well developed.
Assist in the prevention of common and rare genetic diseases.	It is damaging to embryo as well as to the mother.
Assists in the prevention of disorders linked to the mitochondria.	People with disabilities may be affected by devaluation.
Aid in the reduction of the risk factors for the diseases in future generations.	Only wealthy people can afford the procedure
Increase in life expectancy.	Create disparity within the society.
Prevention of discrimination and assistance to people with disability.	Violates the rights of babies.
Be a positive influence in the child's life.	The gene pool could be affected.
Early control of the child's lifestyle.	A large number of genetic disorders still await explanation.
Role in the better understanding of genetic engineering.	Certain genes can be deleted.

FIRST CREATION OF A DESIGNED BABY IN WORLD

Clustered regularly interspaced short palindromic repeats, or CRISPR, were identified for the first time in 1987 by Ishino et al. within DNA sequences of *Escherichia coli*. This accidental discovery would lay the foundation for a revolutionary gene-editing technology. It wasn't until 2012 that Jennifer Doudna of the University of California, Berkeley, and Emmanuelle Charpentier, then of Umeå University in Sweden, published a seminal Science paper detailing how the CRISPR-Cas9 system could be engineered using guide RNA to cleave DNA with high specificity at targeted locations. Their work demonstrated that this bacterial defense mechanism could be harnessed as a powerful tool for editing genes in living organisms(34). Starting around 2016, Chinese scientist He Jiankui began using CRISPR to edit the genes of embryos from rodents, monkeys, and eventually humans. While the animal experiments led to live births, the human embryos were initially used only for research. However, in 2017–2018, He undertook a controversial experiment to create gene-edited human babies by working with HIV-affected couples in which the fathers were HIV-positive and the mothers were not. Out of eight recruited couples, seven continued, leading to 13 gene-edited embryos, of which two pregnancies occurred (35). In April 2018, twin girls named Lulu and Nana were born through an emergency C-section (36). The embryos had undergone CRISPR editing of the *CCR5* gene on chromosome 3 to delete 32 DNA base pairs, creating the *CCR5Δ32* mutation. This alteration prevents the production of a normal *CCR5* protein, a receptor used by HIV to enter cells, with the goal of making the babies resistant to HIV infection. When He Jiankui announced the birth of the twins in November 2018, it sparked worldwide ethical outrage, as it represented the first case of germline gene editing in humans that resulted in live births (37).

INDIA'S STATUS IN CREATING DESIGNER BABIES

India's position in the field of gene editing remains focused on medical and diagnostic applications rather than on the creation of "designer babies." Today, the Indian approach to gene editing includes the use of Preimplantation Genetic Testing (PGT) which is a process done during in vitro fertilization to screen embryos for genetic or chromosomal abnormalities. However, this process only identifies potential genetic issues—it does not involve editing or modifying the embryo's genes (38). As of now, there are no credible scientific publications or reports indicating that India has conducted germline gene editing in humans resulting in the birth of a baby with an edited genome. India's regulatory framework treats germline or embryonic gene editing as restricted or effectively forbidden. National bioethics guidelines and expert commentary suggest that such practices are banned or heavily constrained, with overlapping and sometimes unclear enforcement mechanisms. This legal and ethical environment makes it highly unlikely for any approved clinical program involving germline editing to take place in India (39). In contrast, gene-editing therapies currently being explored and implemented—both in India and globally—primarily target somatic cells, which do not affect the genetic makeup of



future generations. These include recent advances in CRISPR-based therapies for infants with severe genetic disorders reported around 2025. Such treatments represent therapeutic medical interventions aimed at curing diseases rather than creating heritable genetic modifications, and therefore, they do not constitute the production of “designer babies” (40).

LEGAL STATUS / APPROVAL OF DESIGNER BABIES

No country currently permits clinical use of heritable (germline) genome editing for reproduction: while many nations allow laboratory research on embryos under tight rules, reproductive gene editing that would create heritable changes is effectively banned or tightly constrained worldwide. International surveys and legal reviews conclude there is no country that authorizes germline editing for reproductive purposes (41). Countries such as the United Kingdom permit CRISPR and related research on embryos under license (HFEA oversight) but explicitly forbid implanting edited embryos for pregnancy; the HFEA licenses research only and has recommended law updates for other embryo-research limits (42). In the United States, federal policy and congressional restrictions prevent use of public funds for germline editing and the FDA/NIH regulatory regime effectively bars clinical germline applications; any clinical attempt would face strong legal and regulatory barriers (43). China has tightened national biosecurity and biotechnology rules after the He Jiankui case and enforces strict controls and criminal penalties for unauthorized clinical germline work, even as debate continues over how to regulate future research (44). Many other countries (for example, Canada, India, Japan, most EU states) have explicit prohibitions or strong legal/ethical constraints on reproductive germline editing; some allow non-reproductive embryo research under license while banning implantation (45). Finally, scientific and policy bodies continue to call for moratoria or extended international dialogue (e.g., proposals for multi-year pauses) because of safety, ethical, and governance concerns—so the global consensus remains against permitting “designer babies” via heritable genome editing at present.

Table 3: Global overview of countries involved in germline gene-editing or designer babies research, approval status, and year of development (46)

Country	Status of germline editing (designer babies)	Law/regulation/guidelines	Year	Reference
Germany	Strictly banned	Embryo protection Act & Oviedo Convention	1990 (active)	Council of Europe Oviedo convention
European Union	Mostly banned via Oviedo convention	Council of European Convention on Human Rights and Biomedical.	1997	Council of Europe
Canada	Illegal	Assisted Human Reproductive Act	2004 (active)	Government of Canada 2022
United Kingdom	Research allowed: reproduction banned	Human Fertilization and Embryology Act: HFEA licensing for embryo research	2016	Wired UK 2016
Japan	Research permitted under guidelines; reproduction banned	Science Council of Japan Guidelines	2019	Nature, 2019
Israel	Research allowed under license; no reproductive use	Ministry of Health Ethics Regulation	2020	Genetic Literacy Project, 2021
Russia	Prohibited	Federal Law on Biomedical Technologies	2020	Reuters, 2020
South Korea	Prohibited	Bioethics and Safety	2021	Yonhap News 2021
France	Banned by law	Bioethics Law	2021	European Parliament Report 2022
Australia	Research Allowed: clinical use banned	Research Involving Human Embryos Act	2022	NHMRC 2022
Singapore	Research allowed : clinical germline editing banned	Bioethics Advisory Committee Guidelines	2023	BAC Singapore 2023
South Africa	Research under review: reproduction on banned (debated)	National Health Research Ethics Guidelines	2024	Geneonline 2024

CONCLUSION

In closing, the future of designer baby technologies involves both scientific progress and taking into account ethical considerations. The continued progression of ART, PGD, Embryo selection, and gene-editing technologies such as CRISPR provides hopeful



outcomes for preventing or reducing the possibility of severe genetic disorders in offspring. However, utilizing these technologies for non-medical purposes raises considerable doubts about their safety for human subjects and the promotion of inequality in society. In light of continued scientific research to improve these technologies and prove their clinical safety, it is important to develop appropriate ethical guidelines. A careful and scientific approach towards the future of designer baby technologies would go a long way in ensuring that this technology has positive outcomes for the child and wider society while preventing any form of abuse.

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How to cite this article:

Rama Devi Kornil et al. Ijppr.Human, 2026; Vol. 32 (1): 238-247.

Conflict of Interest Statement: All authors have nothing else to disclose.

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