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Human Rights and Emerging Technologies in India: Legal Perspectives on Human Embryonic Stem Cell Research.

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Abstract:

Human rights and technology share a complex relationship, and the introduction to research in human embryonic stem cell (hESC) research in India has paved the way for more complexity. The article studies the relationship between human rights and technologies, with a particular concentration on human embryonic stem cell research. It explores the legal, ethical, and societal dimensions of hESC research, emphasizing the importance of upholding human rights while navigating the complexities of scientific progress. The article briefly discusses the implications and effects of guidelines provided by the Indian Council of Medical Research (ICMR) and their connection with the international framework. While studying these aspects, research has tried to establish a nexus between ethics and human rights. In conclusion, the article emphasizes the importance of balancing scientific innovation with ethical principles and human rights in the pursuit of hESC research in India. In conclusion, the article summarizes key findings regarding the intersection of human rights, emerging technologies, and hESC research in India and underscores the importance of upholding human rights principles while advancing scientific innovation in the legal landscape.

Keywords: Legal framework, Ethical dilemmas, Regulatory guidelines, Scientific research, Human Embryonic Stem Cells

Introduction:

Divine laws bring human beings closer as they make us understand what is right and wrong, which eventually develops the global society. Ethics became more critical to society's growth and development as it became a guiding scale for human behaviour. Science and technology have advanced rapidly, which eventually gave a boost to development as it became a guiding scale for human behaviour. Science and technology have advanced rapidly, which eventually gave a boost to the development of ethical considerations and created complex moral dilemmas.[1]

The development of human rights is a critical moment in society's advancement. Human rights are fundamental liberties and entitlements that all people are entitled to simply because they are human beings. They are built on the idea that everyone has inherent dignity and worth. The concept of human rights has grown to include a wide range of civil, political, economic, social, and cultural rights in order to meet the changing needs and goals of diverse communities.[2]

Science and research are now essential parts of society's development. They have led to new ideas, progress, and wealth. From healthcare and communication to transportation and farming, the search for scientific knowledge and technological progress has changed every aspect of human life. Scientific research, conversely, mirrors the ideals, objectives, and aspirations of society. Conversely, science and technology are influenced by society. Scientists and politicians are driven by cultural norms, ethical rules, and public opinion as they strive to discover and create novel things.[3]

Biotechnology is a potent discipline that can address pressing issues in areas such as healthcare, agriculture, and environmental conservation. Stem cells possess the remarkable capacity to differentiate into any cell. Studying stem cells offers opportunities for regenerative medicine, disease modelling, and drug discovery. Using human embryonic stem cells raises ethical concerns about science, ethics, and human rights.[4]

Aims and Objectives of Study:

- To Explore the Evolution of Human Rights in the Context of Scientific and Technological Advancements
- To Investigate the Ethical and Legal Implications of Human Embryonic Stem Cell Research in India
- To Assess the Impact of Emerging Biotechnologies on Human Rights

MEANING OF STEM CELLS AND EXTRACTION OF HUMAN EMBRYONIC STEM CELL

A primitive cell that can either self-renew (reproduce itself) or give rise to more

specialized cell types. Stem cells act as an internal repair system, having a great potential to develop into different cell types of the body. Cells are eternal elements of the human body. The human body is a large group of cells capable of functioning correctly. Stem cells are the initial cells that can develop into more specialized cells such as muscle cells, white blood cells, red blood cells, brain cells, etc. When stem cells divide, they either remain as stem cells or become another type of cell. [5]

Two essential properties in Stem cells which differentiate them from other cells:[6]

Firstly, these cells possess the remarkable ability to regenerate themselves through cell division, even after extended periods of dormancy. Secondly, given certain physiological or experimental circumstances, they can be prompted to differentiate into specialized cells with distinct roles within tissues or organs.

Potency Of Stem Cells:- Stem Cells can be divided into four types on the basis of their potency:[7]

- **Multipotent Stem cells**:- Multipotent stem cells refer to a type of stem cells that can differentiate into multiple types of adult cells.
- **Pluripotent Stem Cells:-** Pluripotent stem cells can differentiate into all types of adult tissue cells, as well as extra-embryonic tissue that supports embryonic development.
- **Totipotent Stem Cells:-** Totipotent stem cells can develop into a complete organism with the necessary support from the mother.
- **Monopotent Stem Cells:** Monopotent stem cells are a type of stem cell that is devoted to a specific tissue and can only differentiate into cells of one lineage.

(Source: L.Bacakova et al., 2003)

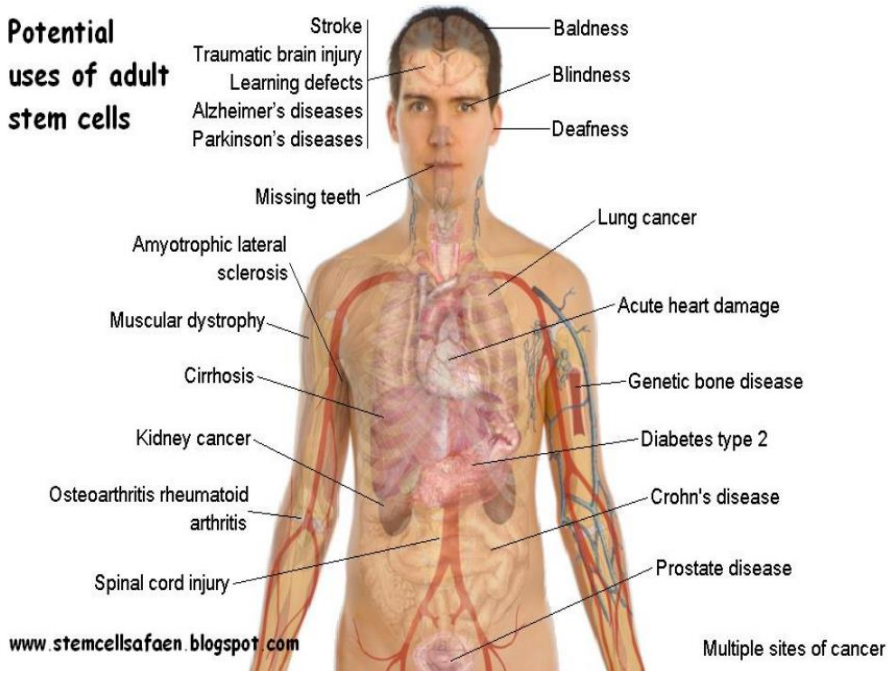
Fig.1. Potency of Stem Cells.[8]

Classification Of Stem Cells: Stem cells are broadly divided into embryonic and adult origin. However, for better understanding, we may divide it into the following groups:-

- Adult Stem Cells
- Fetal Stem Cells
- Umbilical Cord Stem Cells
- Embryonic Stem Cells.
- Induced Pluripotent Stem Cells

Classification Of Stem Cells: Stem cells are broadly divided into embryonic and adult origin. However, for better understanding, we may divide it into the following groups:-

Adult Stem Cells (Somatic or Tissue-specific Stem Cells): [9]



(Source: Stemcellsafaen Blog, 2016)

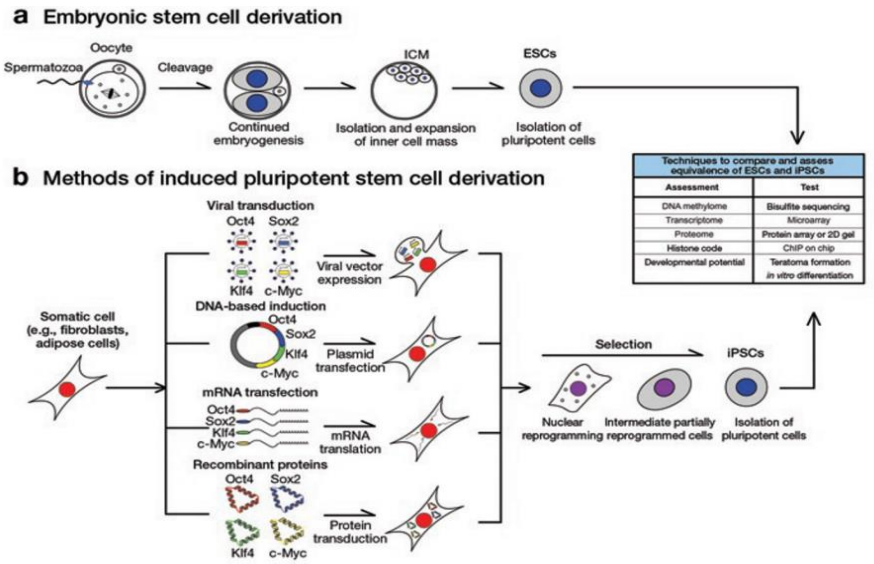
Fig.2. Potential Uses of Adult Stemcells

Sure, here's a paraphrased version: Adult stem cells are present in different parts of the body, like bone marrow, fat tissue, and nervous tissue. They can become a variety of specialized cells within their tissue. Their primary role is to maintain and repair tissues throughout a person's life.

Perinatal Stem Cells: [10]

Stem cells are obtained from tissues surrounding the fetus during pregnancy. These sources include the placenta, umbilical cord, and amniotic fluid. Collectively, these are referred to as perinatal stem cells. They have features of both adult and embryonic stem cells. Depending on their origin, they can be multipotent or pluripotent. Perinatal stem cells are valuable in regenerative medicine due to their accessibility and potential to regulate immune responses.

Induced Pluripotent Stem Cells (iPSCs): [11]



(Source: Dusko Ilic et al., 2015)[12]

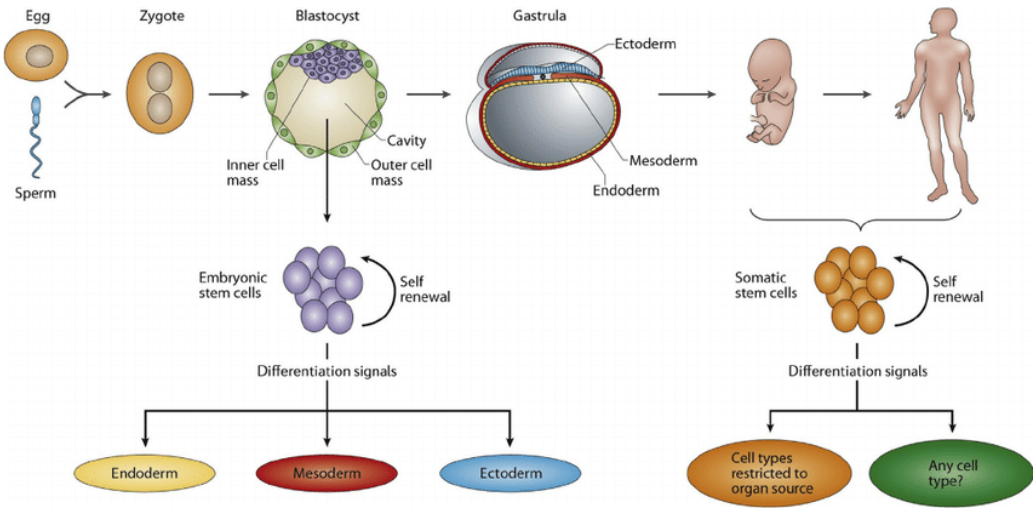
Fig 4: Diagram illustrating the procedures for obtaining human embryonic stem cells (hESCs) and human induced pluripotent stem cells (hiPSCs).

(a) Embryonic stem cells (E.S.C.s) are obtained from the inner cell mass (I.C.M.) of the blastocyst, while

(b) Induced pluripotent stem cells (iPSCs) can be obtained from several types of somatic cells utilizing different reprogramming processes.

By utilizing genetic manipulation, induced pluripotent stem cells (iPSCs) are created from mature cells like skin or blood cells. Similar to their embryonic counterparts, iPSCs possess the remarkable ability to transform into any cell type present within the body. This inherent property allows iPSCs to serve as a powerful tool in disease modelling, drug discovery, and the development of potential regenerative therapies aimed at restoring damaged or diseased tissues.

Human Embryonic Stem Cells (hESCs):



(Source: M.D.Boppart et al., 2015)

Fig.3. Extraction of HeSC. [13]

In 1998, James Thomson isolated embryonic stem cells, sparking disputes over the morality of using embryos for medical purposes. John Gearhart derived germ cells from gonadal tissue that same year, leading to the development of pluripotent stem cell lines from both sources. The blastocysts used for human stem cell research come from in vitro fertilization (IVF) procedures. These stem cells originate from the inner cell mass of a developing embryo during the blastocyst stage. They are pluripotent and capable of differentiating into various cell types in the body.[14]

Human embryonic stem cells (hESCs) are a focus of research due to their potential to model early human development and their promise in regenerative medicine and tissue engineering. Initially, scientists were excited about the potential of hESCs to transform medicine and develop new regenerative therapies. These cells have the unique ability to develop into any cell type in the body, making them a potential source for treating various diseases and injuries. However, ethical and human rights concerns related to the utilization of human embryos in research posed challenges and tempered the initial enthusiasm.[15]

A significant ethical debate about the use of human embryonic stem cells (hESCs) revolves around the destruction of human embryos during the cell derivation process. Concerns arise regarding the moral status of the embryo, the inherent dignity of human life at its earliest developmental stages, and whether using embryos for research conflicts with principles of respect for life and dignity. Critics argue that this practice violates ethical principles and poses dilemmas that need careful contemplation.

Discussions about the ethical complexities in human embryonic stem cell (hESC) research encompassed a wide range of concerns. One key issue was informed consent, specifically how to obtain it properly from donors, especially in cases where the embryos were derived from surplus IVF procedures. Another concern was exploiting vulnerable populations and ensuring equitable access to the benefits of hESC research. Moreover, the commercialization of human embryos raised questions about the commodification of life and the potential consequences on the integrity of research. Given these ethical questions, exploring the implications of human rights within the context of hESC research is essential to navigate the complexities and align scientific advancements with ethical principles and respect for human rights.

HUMAN RIGHTS IMPLICATIONS OF EMERGING TECHNOLOGIES

The emergence of human rights represents a significant milestone in the evolution of societal norms and values, marking a profound shift towards the recognition and protection of fundamental freedoms and entitlements inherent to all individuals. Rooted in principles of inherent dignity, equality, and justice, human rights serve as universal standards that transcend cultural, political, and religious boundaries. The adoption of international conventions and declarations, such as the Universal Declaration of Human Rights (UDHR) in 1948, reflects a global commitment to upholding and promoting the rights and freedoms of every individual.[16]

Human rights principles are essential in guiding ethical decision-making in scientific research. They help protect individuals' rights, dignity, and well-being involved in research studies. Respect for autonomy, the principle of doing no harm, beneficence, and justice are vital ethical considerations that researchers must adhere to. Informed consent, privacy protection, and equitable access to research benefits are crucial aspects of ensuring ethical research practices.[17]

Biotechnology's fast-paced advancements bring both opportunities and ethical challenges. It offers solutions to global healthcare, agriculture, and environmental issues. Yet, as the field progresses, particularly in human-related areas, complex ethical, legal, and human rights concerns arise. A prominent area of debate is human embryonic stem cell research, where human embryos are used and modified for scientific purposes.[18]

International conventions, such as the Universal Declaration on the Human Genome and Human Rights (1997) and the UNESCO Declaration on Bioethics and Human Rights (2005), underscore the importance of respecting human dignity and

protecting human rights in the context of biotechnological advancements, including stem cell research. These conventions emphasize principles such as the primacy of the human person, respect for human vulnerability, and solidarity in the pursuit of scientific progress.[19]

However, the ethical dilemmas surrounding human embryonic stem cell research highlight the tension between scientific innovation and the protection of human rights, particularly the right to life and dignity. Debates persist regarding the moral status of the embryo, the permissibility of embryo destruction for research purposes, and the equitable distribution of benefits arising from stem cell research. Addressing these ethical challenges requires a careful balancing of scientific progress with ethical principles grounded in human rights, fostering dialogue, transparency, and international cooperation to navigate the complex ethical and legal landscape of biotechnological advancements.[20]

LEGAL FRAMEWORK FOR HUMAN EMBRYONIC STEM CELL RESEARCH IN INDIA

When performing human embryonic stem cell (hESC) research in India, various factors such as laws, norms, recommendations, and ethical principles are taken into consideration. The main legal framework governing stem cell research in India is the Indian Council of Medical Research (ICMR) Rules on Stem Cell Research (2017). These rules establish principles and criteria for researching human embryonic stem cells (hESC), with the goal of striking a balance between scientific advancement and ethical considerations, as well as societal values.[21]

In India, hESC research is carefully regulated, following the guidelines set by the ICMR. Researchers in this field must obtain approval from both institutional ethics committees (I.E.C.s) and stem cell research oversight (SCRO) committees. This approval process ensures that research protocols conform to moral standards and regulatory requirements. These committees review and evaluate research proposals, monitor ongoing research activities, and verify compliance with established laws and guidelines.[22]

Aside from the ICMR guidelines, hESC research in India is subject to a combination of laws and regulations connected to healthcare and biomedical research. The Indian Council of Medical Research Act 1985 and the Drugs and Cosmetics Act 1940 establish the legislative foundation for regulating biomedical research and the use of biological materials in research and medical practice. The ICMR and the Central Drugs Standard Control Organization (CDSCO) are regulatory entities established under specific legislation to oversee and control biomedical research operations, including research with human embryonic stem cells (hESC).

Ethical considerations are essential in hESC research in India. The ICMR guidelines emphasize principles like respecting autonomy, doing good, avoiding harm, and ensuring justice. Researchers must get informed consent from donors to collect and use human embryos and stem cells. Donors must understand the research, its purpose, and their rights as participants.

In India, the legal framework governing human embryonic stem cell research (hESC) is meant to ensure ethical research practices. This framework is designed to protect the rights and well-being of research participants, maintain scientific integrity, and promote transparency. With this framework, India aims to encourage responsible and ethical conduct in hESC research while also fostering scientific progress in regenerative medicine and biotechnology.

ETHICAL AND MORAL DILEMMAS:

Research utilizing human embryonic stem cells (hESC) in India presents intricate ethical and moral dilemmas that are shaped by religious, cultural, and societal perspectives. The moral quandary stems from the ethical ramifications of utilizing human embryos in research due to the uncertain moral standing of the embryo. Religious and cultural beliefs majorly influence perceptions of an embryo's moral status, with some traditions attributing personhood and moral values from conception. This raises questions about the permissibility of destroying human embryos for scientific purposes and the ethical considerations of manipulating human life in its earliest developmental stages.

Views on hESC research differ widely across society. Some are concerned about misuse, exploitation, and the commodification of life. Other ethical concerns include consent, privacy, and equal access to benefits. Policymakers, researchers, and stakeholders face a challenging task in balancing scientific progress with ethical and societal values.

RELIGIOUS VIEWS ON STEM CELLS

The debate on the extraction of stem cells mainly revolves around the grounds of morality, as the embryo is destroyed in the procedure of deriving the embryonic stem cells. Religious texts of Judaism, Hinduism, Buddhism, and Islam have expressly talked about the moral status of the use of embryos for therapeutic practices. Judaism emphasizes its aim of saving life and, hence, allows the use of human embryos for therapeutic purposes where the ultimate goal of embryonic stem cell therapy is to cure the sufferer. Judaism does not grant personhood to a fetus that is less than forty days of age.

According to Islam, the soul starts breathing in an embryo only after the 40th day of fertilization, and hence, Islam does not accord the living status to an embryo until then. Islam also permits the use of embryos for stem cell research and therapy.

Hinduism and Buddhism are considered to be strict religions when it comes to the moral status of the embryo, and they do not permit the use of embryos for therapeutic purposes. [23]

Roman Catholic, Orthodox, and conservative protestant churches accord the status of a human being to an embryo from the date of the fertilization of the egg. In contrast, less conservative protestant churches permit research on human embryos before the 14th day from fertilization.

This brief overview of religious views on stem cells points out the contrast among the religions on the moral status of the embryo. In a country like India, where religion plays a vital role in the lifestyle of the citizens, the contrasting religious views on the status of the embryo are somewhat confusing.

UNBORN CHILD, POTENTIAL LIFE, AND EMBRYO- CONFLICTING STATUTORY OVERVIEW

The Indian legal system considers an unborn child and its rights in various statutes. Provisions of these statutes have helped the researcher in interpreting the term ―unborn child and also ―potential life in the fetus‖. Article 21 of the Constitution of India grants and upholds the right to the protection of life and personal liberty of citizens and non-citizens, including unborn children. Apart from the Constitution of India, various legislations also deal with the subject in question. For instance, Section 316 of the Indian Penal Code, 1860 punishes the person responsible for the death of a quick unborn child. Section 416 of the Code of Criminal Procedure, 1973 provides for postponement or reduction of capital punishment of pregnant women with the object of saving the potential life of the foetus and Section 13 r/w Section 20 of Transfer of Property Act, 1882 deals with the transfer for the benefit of an unborn person. [24]

Though the provisions mentioned above recognize the concept of the unborn child, nowhere do they define the term ―the unborn child. Therefore, there has been some confusion regarding the legal status and personhood of the unborn child in India, but amid this uncertainty, the judicial interpretation has come to the rescue. The judiciary has cautiously interpreted the concept of the unborn child in the case of Karnataka State Road Transport Corporation V. Vidya Shinde.[25] In this case, the Karnataka high court held that a fetus that has completed 37 weeks, for all the purposes, shall be considered as a child even though there is stillbirth.

In Oriental Insurance Co. Ltd v. Shantilal Patel [26], the Supreme Court said that an unborn child, from the age of five months until birth, can be considered a legally recognized individual. The phrase "developing ovum" is technically used to describe the organism during the initial seven to ten days following fertilization. An organism is referred to as an embryo from the first week until the end of the second month, and after that, it is referred to as a fetus. An organism is considered a newborn only upon its final emergence from the womb. The court held the belief that the legal recognition of the unborn child and its associated rights and responsibilities should only commence after seven months of pregnancy. This is because premature

birth often occurs during the seventh month of pregnancy, and the kid is still able to survive. Therefore, an unborn fetus from the age of five months until birth should be regarded as equivalent to a living child. In Prakash and another v. Arun Kumar Saini [27], it was determined that an unborn child who has reached the age of five months in the mother's womb till birth should be considered equivalent to a child who is already born. An unborn kid who does not experience live birth can be considered a person who can be held accountable for damages in the event of their death. The fetus is a distinct living being within a woman's body, and the termination of a pregnancy is essentially the loss of a potential child.

On the perusal of the judgments mentioned above, it can be concluded that a fetus aged five months and onwards can be termed an unborn child. Hence, in conclusion, the destruction of a fetus for therapeutic use or the extraction of stem cells before its 5th month could not be construed as the culpable homicide of potential life. The scenario (now) is precise, as the judiciary had specifically differentiated between an unborn child and an embryo. These judgments have made it clear that a woman does not carry a potential life till the completion of five weeks of her pregnancy. This, on the contrary, suggests that from conception till the expiry of the period of five weeks of pregnancy, an embryo does not carry life within itself. Hence, this makes it permissible to support research in the field of embryonic stem cells for therapeutic practices.

These judgments by the judiciary overrule the intentions of the framers of the guidelines of 2007, 2013, and 2017. Alternatively, they permit embryonic stem cell research in a curbed manner so that it is not considered as the homicide of potential life. The analysis of the contradiction between the judicial position and the legislative intent behind the framing of the guidelines banning stem cell therapy depicts the lack of coordination among the three pillars of Indian Democracy.

GOVERNMENT POLICIES AND INTERVENTIONS

India, in 2007, came up with the National Guidelines on Stem Cell Research and Therapy, which was later on in the year 2013 replaced by National Guidelines on Stem Cell Research. The guidelines were the collaborative result of the Indian Council for Medical Research and the Department of Biotechnology. The 2013 guidelines outlawed stem cell therapy and permitted research in the area of stem cells. There was not much change in the 2007 and 2013 guidelines apart from the name. The 2017 guidelines brought up the mechanism of formal committee approval for stem cell activities and their periodic review and monitoring. Guidelines expressly stipulated that the clinical use of stem cells is not permitted, and stem cells must be part of clinical trials approved by the Drug Controller General of India. The guidelines provide the establishment of committees such as the Institutional Committee for Stem Cell Research and Therapy. Any organization interested in carrying out stem cell activities shall be obliged to establish this committee. [28]

National Apex Committee for Stem Cell Research and Therapy: reviews and monitors the stem cell activities at the national level and also approves, monitors and oversees the research falling under the restricted category as well as sets standards for the collection, processing and preservation of human tissues to their assure quality.[29]

The guidelines divide stem cell research into three categories:

- Permissive
- Restrictive
- Prohibitive

And bases themselves on the following principles:

- Health and Safety of donors of the cells.
- Manufacture and quality assurance of stem cell products.
- Type of preclinical studies to be done.
- Designed, conducted, and monitored clinical trials to be done.

Guidelines also attempt to resolve the patent issues regarding stem cells, but the patent clause is so vaguely drafted that it will create chaos in the near future.

The legislative force lacks stem cell guidelines. The guidelines are not binding, and no one can be punished for violating them. The guidelines are nothing but the teeth-less tiger. Another essential flaw of the guidelines is that they fail to distinguish between autologous and allogenic stem cells. Autologous stem cells are the stem cells taken from the patient's own body and administered into his own body. The process of autologous stem cells is 100% safe, and such need not be required to obtain the permission of the Institutional Committee for Stem Cell Research and Therapy.

The new Drugs and Clinical Trials Rules of 2019 attempt to regulate stem cell-related activities by including stem cells under the category of new drugs, but the rules, as per researchers' opinion, are a failed attempt to regulate unregulated!

Delhi High Court, in its judgment, recognized and referred to stem cells and defined treatment as "taking such steps as would not only tend to effect the cure of a disease but also steps which would prevent further deterioration of the disease." If treatment avoids further deterioration of the patient's health and maintains the health status quo, such as proven or unproven, treatment may be offered to the patient subject to the approval of regulating authorities. The judgment of the Delhi High Court, to some extent, supports unproven treatments such as stem cells for diseases that are declared to be incurable. The Delhi High Court's approach is a step forward in the field of stem cell research.[30]

The Indian government has been actively working to address issues surrounding human embryonic stem cell (hESC) research. They have set up regulatory bodies like the Indian Council of Medical Research (ICMR) and the Department of Biotechnology (D.B.T.) to oversee and regulate biomedical research, including hESC research. These bodies ensure that ethical standards and legal compliance are followed by formulating guidelines, regulations, and policies.[31]

To ensure responsible hESC research in India, the government has established guidelines and regulations. The ICMR Guidelines on Stem Cell Research (2017) provide ethical and regulatory frameworks for hESC research, covering principles, requirements, and guidelines for informed consent, donor protection, transparency, and accountability. Additionally, government initiatives support research excellence and capacity building through funding, grants, and collaborations with academic and research institutions to advance hESC research in India.

Although governments have made efforts to address the legal, ethical, and human rights issues in hESC research, obstacles to implementing them remain. These challenges include gaps in regulations, differences in how oversight is done, and stakeholders' apprehensions. Stakeholders worry that the standards for ethics and the law are not being followed. All relevant parties, including decision-makers, researchers, civil society organizations, and other stakeholders, must keep talking, collaborating, and working together to deal with these difficulties and promote responsible and ethical behaviour in hESC research.

FUTURE DIRECTIONS AND RECOMMENDATIONS:

When considering future paths for hESC research in India, those in charge, researchers, and those involved should focus on safeguarding human rights, ethical guidelines, and scientific excellence. It is suggested that the Indian government enhance and enforce regulations for hESC research, ensuring clarity, responsibility, and adherence to ethical principles. Policymakers should also encourage collaboration across disciplines and engage with stakeholders to create discussions, gain public trust, and address issues related to hESC research.

Furthermore, researchers should prioritize ethical considerations in the design and conduct of hESC research, including obtaining informed consent from donors, protecting privacy rights, and promoting equitable access to the benefits of research. Stakeholders, including civil society organizations, religious and cultural groups, and patient advocacy organizations, should be actively involved in shaping policies and regulations related to hESC research to ensure that diverse perspectives and values are considered.

CONCLUSION:

In conclusion, the intersection of human rights, emerging technologies, and human embryonic stem cell research in India presents complex ethical, legal, and societal challenges that require careful consideration and meaningful engagement.

While hESC research holds promise for advancing scientific knowledge and addressing medical challenges, it must be conducted in a manner that upholds human rights principles, respects ethical standards, and fosters public trust.

Moving forward, India must learn from international perspectives, examine best practices, and prioritize ethical integrity and human rights in shaping the future of hESC research. By embracing transparency, accountability, and stakeholder engagement, India can navigate the complexities of emerging technologies in the legal landscape while upholding the principles of human rights and ethical conduct.

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