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WHITE BLACK LEGAL is an open access, peer-reviewed and refereed journal provide dedicated to express views on topical legal issues, thereby generating a cross current of ideas on emerging matters. This platform shall also ignite the initiative and desire of young law students to contribute in the field of law. The erudite response of legal luminaries shall be solicited to enable readers to explore challenges that lie before law makers, lawyers and the society at large, in the event of the ever changing social, economic and technological scenario.

With this thought, we hereby present to you

EMBRYONIC STEM CELL RESEARCH: A CONFLICT BETWEEN THE ETHICAL AND LEGAL NORMS

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Abstract

In 2009, The President of the United States of America, Mr Barack Obama, lifted the ban on federal funding for stem cell research and remarked that medical miracles do not happen simply by accident. They result from painstaking and costly research, from years of lonely trial and error, much of which never bears fruit, and from a government willing to support that work. It is incorrect to assume that an embryo has the same moral status as a fully formed human being. In this pretext, Embryonic stem cell research involves the study of embryonic stem cells (ESCs), which are derived from early-stage embryos. These cells are 4- 5 days old and are unique because they are pluripotent in nature; that is, they have the ability to differentiate into any type of cell in the body (muscle, nerve, blood cells, etc.). Since 1998, this field of scientific research has been associated with serious legal and ethical conflicts. ESCs are usually obtained from in-vitro fertilisation (IVF) clinics, where unused embryos are donated for research purposes, with the consent of the donors. ESCs are harvested from embryos and the practice raises ethical debates about the moral status of the embryo, i.e. Whether the destruction of an embryo to obtain stem cells is equivalent to taking a potential life. The legality of these research practices is also a concern in the field of science as some governments ban it and some fund the same. Public perception also plays a major role in policymaking because societal values can be quite restrictive even when they might not reflect the scientific consensus over the potential benefits of such research. This doctrinal research paper aims to prove the benefits of Embryonic Stem Cell Research and underlines the legal challenges faced by scientists, physicians, researchers, policymakers, and society at large. It is at this juncture we look at this very topic through a scientific eye without being in conflict with the ethical considerations and legal framework that govern our ways.

Keywords

Embryonic Stem Cells; Medico- Scientific Development; Ethics; Legality; Embryo

Introduction

Understanding stem cells is an important facet of this paper. Stem cells¹ are undifferentiated cells capable of dividing and developing into various other types of specialized cells in the body. The major role of a stem cell is to multiply and renew itself, repair damaged cells and tissues, and maintain them. Stem cells are of different types, including adult stem cells, perinatal stem cells, induced pluripotent stem cells, cancer stem cells, mesenchymal stem cells, embryonic stem cells, etc. Embryonic stem cell research, being the specific subject matter, is a developing field of medical science. The word embryo, as we all know, means a fertilised egg as of the first eight weeks of conception. There is a clear distinction between an embryo and a zygote. A zygote is a unicellular organism formed when the sperm fertilizes an egg. In contrast, an embryo is a multicellular organism that has formed after fertilization, and this formation process is called embryogenesis. This is formed through the cell division process of a zygote, which then creates a blastocyte and becomes an embryonic organism, which, upon development, becomes a fetus and then takes the form of a human baby.

Along with this, it is important to understand the process of embryonic stem cell research, i.e., when and from where researchers obtain these cells, which creates controversy. Embryonic Stem cells are derived from blastocysts, which, as discussed earlier, is a week-old embryo that consists of 100-150 cells. Firstly, this research does not take the embryo from a woman's womb to execute the research, which is a common misunderstanding. Human blastocysts have been donated to research facilities from in vitro fertilization clinics with the informed consent of the donors. The eggs are fertilised in the clinics and are used for research without implanting them in a woman's uterus. These cells can survive and grow in special chemical solutions and laboratory Petri dishes. After fertilisation and creation of the blastocyst, scientists remove cells from the inner cell mass region of the blastocyst (a certain number of cells from the centre of the blastocyst out of the 100 cells) to get embryonic stem cell lines. As we already know, embryonic stem cells are pluripotent cells which have the ability to divide into more stem cells or can become any type of cell in the body. Once the cells are removed, the remaining blastocyst

¹ Andrea Vicini, 'Ethical Issues and Approaches in Stem Cell Research: From International Insights to a Proposal' (2003) 23(1) Journal of the Society of Christian Ethics 71 <http://www.jstor.org/stable/23561529> accessed 4th January, 2025.

is destroyed, and the removed cells are placed in a petri dish with nutrients and growth factors. An embryonic stem cell line is created when these cells divide and multiply using the added nutrients. By adding different growth factors, the embryonic stem cells can be induced to develop into different cell types. For instance, if the elements of muscle cells are appropriately added with these ESCs, they can develop into more new muscle cells, which, upon further development, can be used to either replace dead muscle cells in a body or can be used for regenerative medicines.

Benefits of ESC Research

Embryonic stem cells are mostly preferred for research as they are pluripotent in nature. Pluripotent means they are more versatile in nature than adult stem cells. ESCs are derived from a blastocyst's inner cell mass, which is a pre-implantation embryo in the early stage. After the 16-cell stage, the embryo reaches the blastocyst stage 4-5 days post fertilisation. Here, the embryo transits from being 16-celled to 50-150-celled. This stage of embryo shows self-renewal properties and is valuable in scientific fields. The pluripotent character of embryonic stem cells is distinguished from that of adult stem cells, as ESCs are pluripotent. In contrast, adult stem cells are multipotent, producing only a limited number of cell types. Therapeutic concepts for regenerative medicine and tissue replacement after the occurrence of an injury or disease may be based on embryonic stem cell therapies, which have their plasticity and potentially unlimited capacity for self-renewal. Stem cells possess a remarkable ability to replace damaged tissues, making them a cornerstone of regenerative medicine. This is very beneficial for healing wounds and illnesses that cause tissue loss or damage. For example, using traditional therapies for severe burns, spinal cord injuries, and heart illness results in irreversible harm. In this instance, stem cells have great therapeutic potential in promoting the growth of new, healthy tissues, which may improve patients' chances of recovering.

There appears to be great promise for using stem cells to treat neurological illnesses like Parkinson's and Alzheimer's. These illnesses are characterized by the progressive degradation of brain cells, which results in an irreversible loss of motor and cognitive function. By replacing damaged brain cells, stem cell therapy improves neurological functions and, in turn, improves the quality of life for patients. This new field of study appears to be paving the way for brain disorders that were previously incurable². In tissue engineering, embryonic stem cells are

² RS Mahla, 'Stem Cells Applications in Regenerative Medicine and Disease Therapeutics' (2016) *International*

important as they perform specific biological functions along with self-renewal properties and differentiation into one or more types of cells, making them more versatile than adult stem cells, which show limited functions required for tissue engineering³. The most pressing problems of organ shortage and immune system rejection are resolved by organ transplantation utilizing embryonic stem cells. By using immunomodulation techniques, these organs might be pre-manufactured to be compatible with a larger population. As a result, transplant surgeries become quicker and much more accessible, and it serves as a backup for emergency situations. Scientists can guide embryonic stem cells to differentiate into specific organ cells, such as liver or kidney cells. By providing the right environment and scaffolding, these cells can form an entire organ. These Organs grown in the lab from the recipient's genetic material ensure compatibility, which reduces the risk of immune rejection. A consistent supply of lab-grown organs would decrease transplant waiting times and potentially save thousands of lives. This approach also reduces the dependency on living or deceased donors and addresses the growing demand for transplantable organs globally. Since the new organ is derived from the recipient's cells, it is recognized as native by the immune system. As a result, patient outcomes and transplant success rates have significantly increased.

In fact, research on embryonic stem cells contributes to the creation of therapies and the trend toward personalized treatment. The patient is a recipient of customized medicine if his own stem cells allow for treatment that is specifically targeted at his genetic and cellular composition. The use of stem cells in drug research has revolutionized the pharmaceutical sector. As scientists investigate how medications can impact particular human cell types without resorting to human or animal testing, embryonic stem cells have proven crucial in the creation and evaluation of novel medications. When creating medications that are not just effective but also less likely to have negative effects on people, this method is safer and more successful. Scientists utilize stem cell-derived heart cells to test new medications for heart diseases, reducing the reliance on animal models⁴. Stem cells help us in the understanding of the development of many diseases. Various molecular mechanisms underlying diseases, including cancer, diabetes, and neurological disorders can be better understood by the researchers utilizing stem cells to model diseases in the lab. This is essential for refining

Journal of Cell Biology <https://doi.org/10.1155/2016/6940283> accessed 5th January, 2025.

³ Benefits of Embryonic Stem Cell Research (2003) *Improving the Environment for Intercontinental Exchanges* https://ciaotest.cc.columbia.edu/olj/uaic/uaic_summer2003/uaic_summer03_07.pdf accessed 5th January, 2025.

⁴ Benefits of Embryonic Stem Cell Research (2003) *Improving the Environment for Intercontinental Exchanges* https://ciaotest.cc.columbia.edu/olj/uaic/uaic_summer2003/uaic_summer03_07.pdf accessed 5th January, 2025.

existing treatment modalities and creating new therapeutic tactics⁵. In reverse ageing, preliminary studies indicate that stem cells may play a role in reversing the ageing process. The greatest contribution of stem cell therapies may be to healthier ageing and perhaps even the human lifespan. The emerging field promises to address decline with age and improve longevity. Genetic conditions, including muscular dystrophy and cystic fibrosis can be treated using these cells. Researchers will replace faulty cells with functional ones by genetically modifying stem cells to correct defects. This is one of the most innovative approaches mankind has taken toward personalized medicine and gene therapy⁶. Research on embryonic stem cells is a fascinating area with the potential to revolutionize medicine wholly. It addresses some of the most critical questions of chronic illness treatment, tissue and organ regeneration, the scarcity of organs, and the invention of new drugs. The unmatched scientific promise gives hope to millions suffering from currently incurable diseases.

The Conflict: Legality v/. Ethics

There are a lot of ethical and human rights concerns and considerations behind this research. Persons and organisations have persistently prevented and barred ESC research from functioning effectively due to the general public perception of immorality. Friedrich Nietzsche and several other philosophers emphasise that morality is influenced by the nature of our society and our environment. These moral rules keep changing depending on the rules and values that change with time. Due to the nature of this concept, our legal frameworks cannot depend on the same because “One person's morality is different from another’s morality”, and if this prevails, society will be in chaos. Philosophers and proponents of social science like Hart⁷, Austin and Fuller have attempted to define law and the application of morals in the same way to avoid arbitrariness and misuse of law and to create a uniform system. Though the law does not have a specific definition, a synthesis of modern perspectives describes it as a system of rules established by a legitimate authority to regulate human conduct, ensuring justice and maintaining peace and order in society⁸. It is reasonable to understand that the law should be just, fair and reasonable. Still, the above claim of preventing researchers from attempting an action to benefit a larger population is not a moral action.

⁵ ‘Benefits of Stem Cells’ (DVC Stem, [Oct 9, 2024]) <https://www.dvcstem.com/post/benefits-of-stem-cells> accessed 5th January, 2025.

⁶ Louis A Cona, '15 Benefits of Stem Cells: Explained (2024)' (DVC Stem, 9 October 2024) <https://www.dvcstem.com/post/benefits-of-stem-cells> accessed 5th January, 2025.

⁷ HLA Hart, *The Concept of Law* (PA Bulloch and J Raz eds, 2nd edn, Clarendon Press 1994) 185.

⁸ Henry Sidgwick, *The Elements of Politics* (2nd edn, rev, Macmillan 1897)

Philosophers in the deontological line of philosophy, like Immanuel Kant, emphasise the type of actions, which can be good or bad is categorised on the basis of certain moral rules, irrespective of their outcome. Meanwhile, thinkers like John Stuart Mill and Jeremy Bentham⁹ focus on the end outcome, i.e., they judge morality on the basis of the greater good that has been achieved through those actions. Some religious believers profess that life begins from conception and that it has the equal right to life as any other human being. People like them uphold sanctity in everything they see and touch but do not see the benefits or the advancements of science which can save a million lives. It is true that there are other stem cells which can be used for the benefit of people, but there are domains that can only be touched by embryonic stem cells and not any stem cell. The ethical concern, as we have discussed, is that ESC Research¹⁰ is conducted through the killing of life, but the authors of this paper, from the perspectives of researchers and scientists, oppose this fanatic morality principle as it is a mere cell from our human body that can change the lives of many. The blastocysts, which are washed out in this process, are not taken out from a female's womb, replacing research over a child that is to be born to that female. The fertilisation process itself is done in these in vitro fertilization clinics with the consent of the donors. Not all eggs and sperm of two individuals need to be fertilised. Couples or individuals who sign up for pregnancy through IVF facilities seek only one child through the process, whereas there are a million eggs and sperm of the same individuals that can be used for something productive rather than washing them down the drain.

International Frameworks and Viability

Stem cells are highly useful in scientific research; two of the most common ones are adult stem cells and embryonic stem cells. Comparatively, embryonic stem cells are preferred over adult stem cells as they possess the versatility needed in research work. They have self-renewal and pluripotency properties, making them more valuable than adult stem cells. However, because it presents ethical questions, the use of embryonic stem cells has frequently proven contentious, and diverse nations have diverse perspectives on these issues since some find the concept acceptable while others do not. As a result, the nations have different national regulatory approaches and guiding concepts. Global regulations on embryonic stem cell research are supported by certain common concepts, notwithstanding the various cultural values and legal

⁹ HJ Randall, 'Jeremy Bentham' (1906) 22 LQR 311

¹⁰ Thomas Banchoff, 'The Ethics of Embryonic Stem Cell Research' in *Embryo Politics: Ethics and Policy in Atlantic Democracies* (1st edn, Cornell University Press 2011) 120–168 <http://www.jstor.org/stable/10.7591/j.ctt7v8m6.7> accessed 4th January, 2025.

viewpoints of various nations¹¹. Many countries acknowledge the embryo's unique moral standing while permitting study and having a cautious approach¹². This ensures that respect for human life and dignity is maintained, keeping this in mind while the research is permitted, which is still under strict oversight. Respect for human life also means that donors must have given free and informed consent. It is ensured that there must be voluntary and informed consent from the donors of the gametes (embryos), which is essential to ethical practice. Research protocols are frequently necessary to show a great deal of promise for scientific or clinical improvement. The researchers must demonstrate that the research has the greatest possible value and the least amount of harm. States that permit ESC research also forbid the sale or commercialization of gametes and embryos and guarantee that the study will only be carried out for scientific purposes. As a result, commercialization is avoided.

In UK, the Human Fertilization and Embryology Act of 2008 is an act to amend the Human Fertilization and Embryology Act of 1990 and the Surrogacy Arrangement Act of 1985¹³. According to the Department of Health of the UK, The HFEA 2008 Act has various provisions with respect to the use of consent to use or store embryos or gametes, etc. The amendment of the act mainly has many motives, one of them being subjecting the use of human embryos to regulation, irrespective of the process used to create the embryo. The UK also supports therapeutic cloning and the creation of embryos specifically for research, provided it aligns with the license. In the USA, ethical discussions on various aspects of embryos' moral standing are still ongoing. In general, the nation has a wide range of opposing opinions regarding abortion and an embryo's right to life. In the event that the clone is subsequently aborted and used for medical study, the bill S1909/A2840 would legitimize the act of cloning a human embryo and implanting it into a womb¹⁴. Although France is recognized for continuously prohibiting the majority of ESC research, a recent legal change allows certain therapeutic research under strict guidelines. Although there are many limitations, Article L2151-3 forbids the sale of embryos, preserving the scientific integrity of the study. Other articles, such as

¹¹ Andrea Vicini, 'Ethical Issues and Approaches in Stem Cell Research: From International Insights to a Proposal' (2003) 23(1) *Journal of the Society of Christian Ethics* 71 <http://www.jstor.org/stable/23561529> accessed 4th January, 2025.

¹² 'INTERNATIONAL PERSPECTIVES ON HUMAN EMBRYO AND FETAL TISSUE RESEARCH' (1999) <https://biotech.law.lsu.edu/research/nbac/briefings/may99/ip.pdf> accessed 6th January, 2025.

¹³ UK Department of Health, 'Mental Health Act 2007' (Archived 3 January 2013) https://webarchive.nationalarchives.gov.uk/ukgwa/20130103005155/http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/Actsandbills/DH_080211 accessed 6 January 2025.

¹⁴ 'S1909/A2840', *Wikipedia* (last modified 6 January 2025) <https://en.wikipedia.org/wiki/S1909/A2840> accessed 6 January 2025.

Article L2151-5, outline other requirements for submitting a protocol for a research exception to the Biomedicine Agency¹⁵. The NHMRC has created standards for research with embryonic stem cells. The use of spare in vitro fertilized embryos as the source for stem cell extraction is permitted under these NHMRC guidelines. Creating embryos specifically for research purposes is permitted but tightly controlled¹⁶.

The Embryo Protection Act of Germany is one of the strictest acts globally, whose core provision is the prohibition of improper use of embryos. This act provides that the use of embryos for purposes other than pregnancy, such as for commercial use or even research purposes, are prohibited in Germany. The cloning and creation of hybrids involving human embryos are explicitly banned. Not only does Germany have strict rules, but also strict penalties like violations, including improper use of embryos or unauthorized fertilization, can lead to imprisonment of up to 5 years or significant fines. Artificial alteration and germline modification of human cells are prohibited unless the modified cells are explicitly excluded from use in implantation or fertilization. This framework shows Germany's highly restrictive stance on embryonic stem cell research while emphasizing the protection of embryos and keeping ethical considerations in mind while limiting scientific exploration¹⁷. Meanwhile, in the case of India, embryonic stem cell research is regulated by the National Guidelines for Stem Cells Research [NGSCR]. These rules and principles ensure that ESCs are safe and responsible. It also ensures that it shall not be exploitative or immoral through their adherence to ethical and scientific regulatory standards. Stem cell research is classified into three categories: permitted, restricted, and prohibited. This provides a clear framework for overseeing the research. A national level monitoring and guidance is provided for research activities by the National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT). In contrast, the Institutional Committee for Stem Cell Research (IC-SCR) oversees research at the institutional level and ensures compliance with the national guidelines. The ESC research in India reflects many ethical principles. The donor must give his or her informed consent, and the information must be given in a language that the donor can understand to ensure that the research remains

¹⁵ Flegal KM, Kit BK, Orpana H, and Graubard BI, 'Association of All-Cause Mortality With Overweight and Obesity Using Standard Body Mass Index Categories: A Systematic Review and Meta-analysis' (2013) JAMA <https://pmc.ncbi.nlm.nih.gov/articles/PMC3869533/> accessed 6 January 2025.

¹⁶ National Bioethics Advisory Commission, *Intellectual Property and Biotechnology* (May 1999) <https://biotech.law.lsu.edu/research/nbac/briefings/may99/ip.pdf> accessed 6 January 2025.

¹⁷ Federal Ministry of Health (Germany), 'Act on the Prevention and Control of Infectious Diseases in Humans (Infection Protection Act)' (10 December 2014) https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/E/ESchG_EN_Fassung_Stand_10Dez2014_01.pdf accessed 6 January 2025.

transparent. Researchers and institutions are expected to have a high ethical standard and transparent process while also strictly maintaining the non-commercialization of the embryos and stem cells¹⁸.

There have been various debates about the moral status of the embryo. While countries like Germany view embryos as having full human rights and warrant strict protections, other countries like the UK and Australia consider embryos to have special yet not equivalent status as of a fully developed human, allowing conditional research. Technologies involving genetic modifications in embryos like CRISPR-Cas9 hold the potential to treat hereditary diseases, but they also raise ethical concerns about “designer babies”. A designer baby is one whose genetic makeup has been selected or altered, often excluding a particular gene associated with a disease. While nations like the UK allow basic research on genome editing but prohibit its clinical application, other nations like France and Germany strongly oppose any form of germline modification¹⁹.

Conclusion

One man’s ethics is different from another man’s ethics. Ethics is a very subjective concept, which varies from domain to domain. Every job in India has its own set of ethical considerations that must be followed to profess that particular job freely. Indian medical sciences also have a set of ethics that every doctor, practitioner, and researcher must follow to maintain the sanctity of this profession and provide efficient and trustworthy service to the people of this nation. However, these guidelines and moral principles have been established to maintain order and avoid exploiting patients and people in this discipline. Like we have laws to regulate the conduct and behaviour of people, we have ethical guidelines in every domain which are to be followed. As stated earlier, ethics is a subjective concept and our subject matter at present is a set of ethical barriers to embryonic stem cell research. Every practitioner in this research also upholds certain ethical values, such as using the embryos and samples only for the greater good and not for their personal gain or to harm society in any manner. The kind of ethical concerns raised by critiques majorly involves primarily about the taking of a life, which has been clarified that it cannot amount to the killing of a human because it is merely a

¹⁸ Department of Biotechnology, Government of India, 'National Guidelines for Stem Cell Research - 2017' (2017) https://dbtindia.gov.in/sites/default/files/National_Guidelines_StemCellResearch-2017.pdf accessed 6 January 2025.

¹⁹ National Bioethics Advisory Commission, *Intellectual Property and Biotechnology* (May 1999) <https://biotech.law.lsu.edu/research/nbac/briefings/may99/ip.pdf> accessed 6 January 2025.

unicellular organism and has not taken the form of a human child. If critiques are going to uphold the value of a cell, then they shall also consider the number of ants and mosquitoes which are killed on an hourly basis worldwide for no purpose, which are rather multicellular organisms. Other concerns include the trial process i.e. even if researchers find a cure to a particular disease, how can we be sure that it can work successfully on a human being? Like any other medicine that was invented and tested, it shall pass several stages, starting from the identification and testing of chemical compounds, animal testing in multiple doses, and then on people from 1-2 to 10-20 and 50-100 sample basis. Agencies like the FDA and CDSCO shall finally test it, and only after approval shall it be ready for supply or treatment. In conclusion, the world is developing rapidly, and currently, we are facing the AI generation where everything is being automated. The medical field cannot fall behind, for which we need to experiment and explore all the possible domains and methods of science in order to be ready for future threats. Embryonic stem cell research is a high-potential research field that can yield exponential results if experimented with and tested correctly.

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