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Stem Cell Research-Ethico-Legal Perspectives: Protection of Human Embryos

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ABSTRACT

Stem Cell technology is a rapidly developing field that combines the efforts of Cell biologists, geneticists and medical practitioners, offers effective treatment for a variety of malignant and non-malignant diseases because their stimulation can be accelerated to develop into any type of cell or tissue or organ system. The Article studies the latest development in medical sciences is the use of Stem Cell therapy. There are serious ethical and religious questions involved in the use of embryo Cells as it could be considered as feticide because of the belief that life begins at conception. So the next best thing to go with the research of umbilical cord blood. Scientists believe that several incurable diseases can be treated and even cured by Stem Cell therapy. For this purpose, Stem cell banks have been set up in big cities like Chennai and Mumbai In these banks Stem Cells of newborn babies will be preserved for twenty years or more in liquid nitrogen. Rich Indians have accepted Stem Cell therapy as a health insurance cover for their progeny. Medical experts and Stem Cell banks claim that stored stem cells can cure Seventy life-threatening diseases including diabetics, leukaemia, blood cancer, and Alzheimer's diseases. As Civilization progressed, the man had to fight against diseases caused by both external and internal agents. So he had to invent and prepare curative and preventive medicines by using intellectual mind performing through Researches.

Key Words: Cord blood Cells, Ethical and moral and legal, Foetus, Human Embryonic Stem Cells.

INTRODUCTION¹⁻⁵

Research on human subjects involving cells and tissues derived from human embryos and fetuses must safeguard human rights, dignity, and fundamental freedom. This includes processes related to obtaining human tissues and cells for research, diagnosis, and therapy. The fundamental tenets of beneficence, non-maleficence, justice, and autonomy should be adhered to in all research involving human subjects. To achieve these objectives, all research involving the use of stem cells must be guided by the general principles laid down in the Ethical Guidelines for Biomedical Research on Human Participants published in 2006 by the Indian Council of Medical Research (ICMR) and specific principles related to stem cells as provided under these guidelines must be followed.

Scientists began to investigate the possibility of Stem cell-based therapies to cure disease, which is often referred to as regenerative medicine. The major conflicting unethical issue identified with this research is the extraction of embryonic stem cells by embryo destruction. The very embryo which

can become a human being is destroyed at the onset of its potentiality of becoming one of us. Any research which stands to violate these principles is bound to suffer from moral and ethical controversies. The main goal of Human Embryonic Stem Cell Research is to identify the mechanisms that govern cell differentiation and to turn HESCs into specific cell types that can be used for treating debilitating and life-threatening diseases and injuries.

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SOURCES AND TECHNOLOGY

Human Embryonic Stem Cells

HESCs re-derived from the inner cell mass of the human blastocysts. A blastocyst is formed five days after fertilization of

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the egg by the sperm. It has an outer shell that matures and if survives implantation becomes placental tissue and the inner cell mass becomes the tissues of the human body. The extraction of HESCs from inner cell mass for research purpose leads to the destruction of the embryo. The major source of human embryonic stem cell tissues are the spare or supernumerary embryos created during *in-vitro* fertilization as a part of infertility treatment. The other source is creating embryos with somatic cell nuclear transfer techniques (SCNT). The legislation of most countries including India allows the use of spare or supernumerary embryos either fresh or frozen created during *in-vitro* fertilization. Some countries with a more liberal view have allowed the creation of human embryos with SCNT as a source of embryonic tissues. The controversial issue in embryo research is concerned with which embryos are suitable and can be used for research.

There is disagreement over whether it is appropriate to create embryos solely for research purposes, and what techniques should be used to create those embryos. Many people and government feel that an appropriate restriction on embryo research is to limit the use of embryos in research to those embryos that are surplus to infertility treatments.

Legal Perspectives

The extraction of embryonic tissue for research purpose involves the destruction of the embryo. Most of the arguments about the rightness and wrongness of embryo destruction are based on the moral status of the embryo. The moral wrongness associated with embryo destruction will not only make the research impermissible but also deny the potential benefits expected from this research.

Using human embryonic tissues for research poses a moral problem as it brings two highly valued but conflicting moral principles. The objective is to provide treatment to ease pain and suffering on one hand and the value of human life and dignity on the other. The extraction of stem cells from human embryos violates the second principle as it leads to the destruction of potential human life. Both principles cannot coexist together, but which principle takes precedence is a rather contentious issue. The embryo should be considered from the moral or legal point of view as the main debatable issue associated with HESC research.

The HFE Act, 1990 permits research to be licenced on embryos until the formation of a primitive streak. That is taken to occur not less than fourteen days after fertilization.

The HFE Act imposes several important restrictions on the use of embryos in research. These include the following:

- i. An embryo cannot be stored or used for research after the primitive streak, which is taken to be fourteen days from the mixing of gametes.
- ii. The use or storage of an embryo requires a licence and

licences can only be issued by the HFEA for certain purposes including Promoting advances in the treatment of infertility, miscarriages, contraception, or causes of congenital diseases. Human Fertilization and Embryology Act 2008 has added three new purposes to the original five sets out in the Act: Increasing knowledge about the development of embryos, serious disease, or enabling the application of any such knowledge in developing treatments for serious disease.

- iii. It is not permitted to mix human and animal gametes or to place a human embryo in a non-human animal, except as permitted by the HFE Act 2008.
- iv. The HFEA will only consider licences for research if a Research Ethics Committee has approved the research.

Controversially the HFE Act permits research not only using embryos that are 'spare' following infertility treatment but also on embryos that are specifically created for research.

Most people who support research involving embryos, including the Warnock Committee whose report underpins the HFE Act, require that embryos be treated with respect. The House of Lords Committee on Stem Cell Research recently concluded that the HFE Act does demonstrate respect for the embryo used in research, for example, by only allowing embryo research to be performed where no alternative means are available, and only for one of the permitted purposes

The HFE Act 2008 inserts a new section 4A into the 1990 Act:

- 1) No person shall place in a woman-
 - a) A human admixed embryo,
 - b) Any embryo that is not human,
 Any gametes are other than human gametes.
- 2) No person shall –
 - a) Mix human gametes with animal gametes,
 - b) Bring about the creation of a human admixed embryo, or
 - c) Keep or use a human admixed embryo, except in pursuance of a licence.
- 3) A licence cannot authorize keeping or using a human admixed embryo after the earliest of the following-
 - a) The appearance of the primitive streak, or
 - b) The end of the period of the two weeks beginning with the day on which the process of creating the human admixed embryo began, but not counting the time during which the human admixed embryo is stored.
- 4) A licence cannot authorize placing a human admixed embryo in an animal.

So the Act only allows the creation of admixed embryos up until the age of 14 years and does not allow such embryos to be placed in a woman. The creation of admixed embryo is only permitted if done under a licence.

Research-Phase	Ethical issues
Donation of biological materials	Informed and voluntary consent
Research with HESCs	Destruction of embryos Creation of embryos specifically for research purposes 1. Payment to oocyte donors 2. Medical risks of oocyte retrieval 3. Protecting reproductive interests of women in infertility treatment
Use of stem cell lines derived at another institution	Conflicting legal and ethical standards
Stem cell clinical trials	Risks and benefits of the experimental intervention Informed consent

It's very difficult to ascertain the moral status of the embryo as it varies. There are different opinions about this moral status. The leading persuasion deliberate that the embryo has the status of Persons, or Potential persons, or Divine creations, or Subjects of moral harm, or the beginning of human life with intrinsic value, or organic material with no moral standing than other body parts. The development of human life or person is an evolving process starting from fertilization to the birth of a newborn.

The early stages of development mostly compromise cellular differentiation whereas, in the end, the fetus assumes its full form both in physical and functional status.

There is no clear-cut demarcation during this process of physical development as to when personhood is acquired. At one end of the horizon of purviews on this issue is the belief that the embryo, from the moment of conception, is created by God and is an individual who possesses their rights with the equal moral status as an adult human being. Those who hold this horizon, such as Catholic Bishop Richard Doerflinger, says that it is wrong to destroy embryos of any gestational age, for any purpose. This absolutist view is not shared by all those with religious beliefs.

A substitute stance is that the embryo acquires a full personal identity, and the ethical rights that come with this status, step by step during the process of development occurring between conception and birth. It is so ethically acceptable, under these circumstances, to use embryos for research purpose. This read has been defended by some theologians of alternative faiths, together with Protestant, Christians, Jews, Muslims and Buddhists, and is additionally seconded by many folks who don't have religious faith.

The embryo in its early stage is a cellular structure and don't have the psychological, physiological, emotional and intellectual characteristics that we tend to attribute with individuality. Consequently, traces that if the human embryo

does not fulfill the standard measure for personhood it does not possess any interests to be protected and thus may be instrumentally used for the benefit of other human persons. In the discussion about embryo research, the formation of the primitive streak is considered an important landmark point. The primitive streak, seen in the form of appearance of a surface thickening, is the first visible organization of the embryo which usually happens around fourteen days after fertilization.

The primitive streak, seen in the form of appearance of a surface thickening, is the first visible organization of the embryo which usually happens around fourteen days after fertilization. The term 'pre-embryo' was introduced in 1985 to describe the early embryo up to this point. One argument that was used to justify distinguishing the pre-embryo and the embryo proper was that the possibility of splitting the pre-embryo into two parts or twin parts. It appears, as per this argument, that the pre-embryo wasn't a person, as personhood is commonly taken to imply indivisibility or individuality. Others have argued that the concept of the pre-embryo is a rhetorical device invented to justify embryo research and that it creates an artificial division in what is, in reality, a continuous biological process of development. Some research workers argue that the formation of the central nervous system should be considered as the watershed for the definition of life since this implies that the possibility of sensation initially exists.

Up to 14 days of the embryonic period, the blastocyst has no central nervous system and therefore, cannot be considered as sensate. If we can remove organs from brain dead declared patients who are alive in some sense, then we can use two hundred-cell embryos as cell donors at the same moral status as brain dead individuals. It is argued that the early-stage embryo is not sufficiently personalized to possess the ethical and moral weightage of personhood.

Global Legislation Governing Embryonic Stem Cell Research

Legislation governing human embryonic stem cell research is not uniform and varies from country to country. Most of them have allowed the use of spare or supernumerary embryos created during *in-Vitro* fertilization for this purpose but have prohibited the creation of human embryos specifically for research purposes. The use of spare or excess embryos is subjected to certain provisions like informed consent, donation of embryos without financial compensation and restrictions on the use of embryo not beyond fourteen days¹.

Few countries have put prohibitions on buying and selling of gametes, fertilized eggs, embryos and foetal tissues. But some countries with a more liberal view have allowed the creation of human embryos for research purpose by somatic cell nuclear transfer technique.

India has allowed the establishment of new HESC lines with spare, supernumerary embryos with prior approval of the Institutional Committee for Stem Cell Research and Therapy and Institutional Ethics Committee.²

Need for Definitive Legislation:

Since the spare embryos created during infertility treatment are the most valuable source of embryos, India lacks in having definite legislation regulating artificial reproductive technologies (ART). The existing guidelines directing stem cell research including embryonic Stem cell are prepared by the Indian Council for Medical Research. These recommending guidelines have two inherent defects. One, these guidelines do not have any legal effect and second, it has no penal provisions for violating the rules/policies mentioned in these guidelines.

The absence of effective legislation will raise serious objection regarding the rights of the donor of embryos, the number of spare embryos, quality of the embryos, preservation, and disposal of frozen embryos etc. The presence of definite enactment will help to regulate the activities of ART clinics by imposing strict accountability and responsibility through penal provisions. Registration of ART clinics should be made mandatory and subjected to periodic supervision to ensure a high standard of norms, care, quality of treatment and facilities offered by them specifically because of use, disposal and preservation of embryos.

The rights and autonomy of the donor couple and donor of gametes should be adequately protected. Informed consent of the donor regarding the use and destruction of the spare embryo should be taken. The question of financial compensation given to them should be adequately addressed keeping into mind the relevant existing rules and regulations of the country. Legislation similarly on the lines of the Human Fertilization and Embryo Act, as prevalent in the United Kingdom, will help to lessen the problems associated with ART.

Legal and Constitutional Status of the Embryo/ Unborn Foetus:

All humans are born free and equal in dignity and rights.³ The word born was used to exclude the foetus and embryo from granting human rights. An amendment was suggested and rejected that would have deleted the word “born”, as it was deliberated to protect the right to life from the moment of conception.⁴

Even the Convention on the Rights of the Child does not recognize the right to life until birth. Thus, a foetus has no rights under UDHR. The main standard for the protection of human life in general international law is Article 6 of (CCPR). Article 6 of the CCPR, in its first paragraph the norm prescribes that every human being has the inherent right to life. However, the phraseology of the norm doesn't outline the term

“human being.”⁵

The unborn foetus has the full potential to become a human being in the right environment. In the liberal interpretation of the above fundamental right, one can conclude that the unborn foetus, from conception to birth, has a right to life and it is immaterial whether the foetus is created in vitro or in vivo. Now, if this standard was applied to all forms of unborn life, not only would research with embryonic stem cells infringe upon art.⁶ CCPR, but the legality of abortion laws would also be highly debatable.

The US Judiciary system has never ruled on the constitutional status of embryos outside of the body and most US states have no law on the matter. But the court has ruled that foetuses are not persons within the meaning of the 14th Amendment, and thus do not have constitutional rights as such. Presumably, that ruling would also extend to embryos as well.⁶

The person's right shall be protected by law and, in general, from the moment of conception and not to be deprived of his life.⁷

But the Inter-American Commission on Human Rights, one of two adjudicatory bodies that interprets and monitors compliance with the American Convention, has clarified that this protection is not absolute. But the Inter-American Commission on Human Rights, one of two adjudicatory bodies that interprets and monitors compliance with the American Convention, has clarified that this protection is not absolute.⁸ Everyone's right to life shall be secured under law as provided under the European Convention on Human Rights provides.

In *Paton v. United Kingdom*, held that the Convention language “tends to support the perspective under Art 2 and acknowledged that recognition of an absolute right to life before birth would be averse to the object and purpose of the Convention.

In *Vo v. France*, the European Court of Human Rights, which interprets and monitors compliance with the European Convention, affirmed that “the unborn child is not regarded as a ‘person’ directly protected by Article 2 of the convention and that if the unborn do have a ‘right’ to ‘life,’ it is implicitly limited by the mother's rights and interests, including her rights to life, health, and privacy.” The above judgment brings forth another controversial issue of foetal rights versus maternal rights of autonomy. The liberalized abortion laws existing in different countries and so proposed by various organizations have determined the precedence of maternal rights over foetal rights.⁹

The fundamental right to life is guaranteed under Article 21 of the Constitution of India that no person shall be deprived of his life or personal liberty except according to procedure established by law. Even here the term “person” is not de-

fined. The Indian Legal System provides for the protection of the rights of the foetus through provisions provided under the Indian Penal Code (IPC) which deals with miscarriage. Section 315 IPC deals with and Section 316 IPC deals with the penal provisions, the unborn child is protected from any act which prevents it from being born and provides punishment for causing its death which is considered equivalent to culpable homicide.

In the above penal provisions, the unborn child is protected from any act which prevents it from being born and provides punishment for causing its death which is considered equivalent to culpable homicide. Section 416 of Code of Criminal Procedure (CrPC) 1973 provides for postponement of capital sentence of pregnant women and to commutes the sentence to life imprisonment in such circumstances. This provision is made to protect the life of the unborn foetus as it has nothing to do with the act committed by the pregnant woman. Here the legislation has considered the unborn foetus as a distinct and separate individual/entity with the right of protection against potential harm.

This provision is made to protect the life of the unborn foetus as it has nothing to do with the act committed by the pregnant woman. Here the legislation has considered the unborn foetus as a distinct and separate individual/entity with the right of protection against potential harm. Here the statute has defined the unborn as a legal person by fiction and acquire benefit in receiving property as transferee. The unborn foetus is protected against potential harming in the same manner as the fundamental rights of non-Interference with personal life and bodily integrity guaranteed to a human person. If the embryo is granted the status of Personhood, then they too will have the right not to be harmed or killed with imposed obligations of not to do so.

With the lack of clarity on the status of the embryo and deliberations put forth by constitutions of various countries and decision given by competent courts, it can be assumed that the foetuses are not the person and hence cannot enjoy fundamental constitutional rights meant for human beings or persons. Though the Indian Penal Code and Code of Criminal Procedure protect the foetus from potential harm the Indian Constitution is silent on this aspect of extending the fundamental rights to the unborn foetus in clear terms. The European Commission states that, despite the diversity of views on the moral status of the human embryo among its member states, one can find two conflicting tendencies emerging concerning the moral position of the embryo and the legal protection which should be afforded the embryo concerning scientific research. These two positions are:

1. Human embryos have the equal moral status as human persons and consequently, are worthy of equal protection.
2. Human embryos do not have the equal moral status as human persons and consequently have a relative worth of protection.

The spare embryos which are the Outcome of infertility treatment are the essential source of embryonic tissue. These embryos can either be used for embryonic stem cell research or can be discarded as leftover material once the objective of infertility treatment is achieved. The transformation of discarded embryos into stem cells has been referred to by one scientist as the process of turning 'garbage into gold'.¹⁰ The child intending couples have to make the emotional, physical and financial investment to reap the benefits in terms of successful pregnancy through this beneficial outcome cannot be always guaranteed. That so considered 'waste materials' has economic value considering the initial substantive financial and emotional/physical cost incurred by these donors. Also, the potential commercial value associated with the result of embryonic stem cell research using such embryos might be tremendous. Pharmaceutical and Biotech companies will earn substantive commercial profit that may eventually flow from this work.

This raises an important query about the right of the donor couple to seek or claim financial stake or compensation. Nevertheless, it is illegal under the Human Fertilization and Embryo Act (HFEA) of the United Kingdom (UK) for them to incur any financial reward for donating their embryos and they have no financial stake in any materials or procedures developed from their donation.¹¹

Most commentators support a ban on the 'sale of embryos. For example, the European Group on Ethics in Science and New Technologies has stated that 'embryos, as well as cadaveric tissues and foetal tissues, must not be bought or sold Measures should be taken to prevent such commercialization.

It is illegal for gametes to be bought or sold. A rising number of biotech and pharmaceutical companies are gathering an array of 'valuable' bodily materials including DNA samples and umbilical cord blood (also used for stem cell research) from various corners of the globe for scientific and commercial exploitation. However, the issue of making payments to gamete donors or embryo donors remains ethically controversial as it may lead to "commodification of the body.

In January 2003, representatives from several countries, including the US, met in London to consider initiating a Human Genome Project equivalent for stem cells. The idea would be to gather results of stem cell research efforts worldwide into a comprehensive stem-cell program with global reach, avoiding the legal quagmires and inefficiencies of each country moving forward independently. Roger Pederson, a senior stem-cell investigator at the UCSF Medical Center who moved to England the advantage of the more encouraging regulatory environment is championing the idea

most vigorously.

Bush's policy has stimulated considerable interest in the private sector to push for and support stem cell research. The foundations which have been established for Medical Research have given tens of millions of dollars to various laboratories, many in Europe. Several universities, teaching hospitals and biotechnology companies have also stepped up their involvement in the field, as have wealthy individuals. Late last year, an anonymous benefactor gave Stanford University twelve million dollars to build a stem-cell research centre, and Andrew s. Grove, the Intel chairman, gave the University of California-San Francisco five million dollars for such a centre.

Exponents and opponents of embryonic stem cell research debate when human life begins, whether destroying embryos amounts to murder, and whether the moral good of deriving medical breakthroughs outweighs the ethical in injunctions.

Therapeutic cloning is not acceptable to those who believe that a human being is created at the instant of fertilization. That belief is powerful and ultimately transcends scientific disagreement. The question is for our democracy on how tightly that spiritual belief should bind the hands of those who disagree with it. Under the Human Fertilisation and Embryo Act, import of embryos or gametes is regulated through the licensing arrangements for embryo research: a licensee who wishes to import embryos or gametes must apply for and receive authorization from the HFEA. Other tissue imports are regulated by the Human Tissue Act 2004, which relaxes the rules ordinarily applying to non-imported material. The rule that tissue may only be used under appropriate consent is specifically abrogated. Nonetheless, the Human Tissue Authority is preparing some guidance on good practice and scientists importing ES cell lines should seek the approval of the Steering Committee of the UK Stem Cell Bank. The regulatory system has thus provided a skeleton framework for monitoring the acceptability of using imported bodily material in stem cell research and therapy.

Others believe that life begins with the emergence of personhood. That is the time when the emerging being first can sense its environment and respond to light, pain, pleasure, sound, and other external stimuli. This occurs many weeks into gestation in humans and far beyond the 5–6-day period when blastocysts would be harvested for stem cells. Indeed, there was a period that even the Roman Catholic church believed that life began at “quickening”, the time at which a mother could sense the movement of an unborn child in the womb. Generally, this occurred around 40 days into gestation or 10 weeks after fertilization, just about the same time the organism ceases to be known as an embryo and is referred to as a fetus. This doctrine was modified in the late 19th century and presently it is thought that life commences now of concep-

tion for those who ascribe to the Roman Catholic faith. It is interesting to note that Sen. Orrin Hatch (R-UT) has personally concluded that life does not begin now of fertilization because there is “zero chance” of becoming a human being until it is implanted.¹² Since implantation happens after the blastocyst stage during which harvesting of stem cells takes place, Hatch is at peace with himself for condoning stem cell research for therapeutic purposes.

The issues which have discussed so far are, for the most part, ones that relate either to embryo research in general or to Embryonic Stem cell research. However, some other issues arise in stem cell research. The important question is whether it is ethical or legal to use imported material where the consent process meets the rules of the country of the collection but not the standards of ethical sourcing that apply in the country of destination.¹²

CONCLUSION

The Universal Declaration of Human Rights states that everyone has right to a standard of living adequate to the health and wellbeing of himself and his family. Art 25(2). Art 39(e) of the Indian Constitution enjoins the State to direct its policies to secure the health and strength of workers. Right to life, one of the fundamental rights, as enumerated under Indian Constitution, maintains the interrelationship between law and medicine. civilization progressed, the man had to fight against diseases caused by both external and internal agents. So he had to invent and prepare curative and preventive medicines by using intellectual mind performing through Researches. Medical jurisprudence deals with those relationships which are generally recognised as having legal consequences. Research on human subjects involving cells and tissues derived from human embryos and fetuses must safeguard human rights, dignity, and fundamental freedom. This includes processes related to obtaining human tissues and cells for research, diagnosis and therapy. The fundamental tenets of beneficence, non-maleficence, Justice, and autonomy should be adhered to in all research involving human subjects. To achieve these objectives, all research involving the use of stem cells must be guided by the general principles laid down Niels Petersen. The Legal Status of the Human Embryo *in-vitro*. in the Ethical Guidelines for Biomedical Research on Human Participants published in 2006 by the Indian Council of Medical Research (ICMR) and specific principles related to stem cells as provided under these guidelines must be followed. The Indian Medical Council for Research finalized a set of guidelines for Stem Cell Research and treatment. It is also planning to set up a National Stem Cell bank to help those who cannot afford the cost.

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